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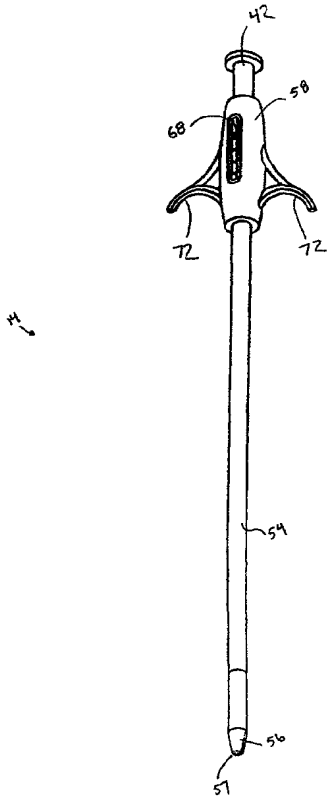

(57) Abstract: An improved vascular incisor (14) and method for allowing a user to safely create an incision in a body lumen. The present invention provides an apparatus which can create in surrounding body structures, such as the back wall of the ascending aorta. The incisor (14) includes a surgical element such as a blade (40) which is activated by an actuator (42). As the actuator (42) is depressed, the blade (40) is moved from a protected, retracted position to an exposed, deployed position. The exposed blade (40) is pushed into a front wall of the ascending aorta to create an incision. As the actuator (42) is depressed further, the blade (40) is automatically moved to the retracted position to prevent the blade (40) from incising the back wall of the aorta.

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VASCULAR INCISOR AND METHOD

BACKGROUND OF THE INVENTION

The present invention is directed to methods and devices for safely creating an incision through a wall of a patient's blood vessel. Such devices and methods are useful for performing various procedures on a patient's vascular system and heart such as the procedures described in U.S. Patent Nos. 5,584,803 and 5,682,906 which describe coronary arty bypass grafting (CABG) and valve procedures, respectively.

Prior to occluding the ascending aorta and maintaining circulation of oxygenated blood, an incision must be made in the ascending aorta and a cannula inserted for return of blood to the patient. However, conventional methods suffer from potentially serious drawbacks. Conventional surgical techniques use a scalpel or knife to create an incision in the front wall of the ascending aorta prior to the insertion of the cannula into the aorta. Such scalpels have the potential to injure surrounding body structures. Additionally, in closed chest procedures, it is difficult and time consuming for the surgeon to separately manipulate both the scalpel and cannula.

Accordingly, there is a need for an incision method and device which can quickly and easily create an incision within the front wall of the ascending aorta through a small incision in the chest rather than a full sternotomy.

SUMMARY OF THE INVENTION

The present invention provides an improved vascular incisor, and cannula assembly and method for allowing a user to safely create an incision and insert a cannula in a body lumen. More specifically, the present invention provides an apparatus which can create an incision in a wall of the ascending aorta and insert a cannula in a fast and convenient single step process. The present invention includes a cannula and an incisor positionable within the cannula. The incisor has a blade which is moved by an actuator such as a trigger or a plunger. As the actuator is depressed, the blade is moved from a protected, retracted position to an exposed, deployed position. The exposed blade is pushed into a front wall of the ascending aorta to create an incision. As the plunger is depressed further, the blade is automatically moved to the retracted position to prevent the blade from contacting other body structures such as the back wall of the aorta. As the incisor is pushed through the incision, the cannula can be simultaneously inserted through the incision in a single step process.

In a first aspect, the present invention provides an incisor for creating a vascular incision. In one embodiment, the incisor has a rod which is movable relative to a body. A surgical element, such as a blade, is disposed at a distal end of the rod. A plunger having at least one finger engages a proximal end of the rod. When the plunger is moved from an undepressed position to a depressed position the rod and surgical element are advanced from the retracted position to the deployed position. The finger engages a ramp so that the fingers disengages from the proximal end of the rod, and the surgical element is moves back to the retracted position. In a specific configuration the incisor has a return spring to bias the plunger to the undepressed position. As the plunger is biased back to the undepressed position, the plunger fingers pass by the proximal surface of the push rod and the resilient spring force contained in the flexed plunger fingers biases the finger radially inward into the initial position and into engagement (or near engagement) with the proximal end of the push rod. At this position, the plunger and push rod are positioned for repeat actuation of the blade.

In another embodiment, the incisor includes a housing and a movable push rod. The push rod is biased toward a retracted position. Actuation of a trigger pin over a ramp moves the push rod and a surgical element from the retracted position towards a deployed position. When the trigger pin reaches a top of the ramp, the trigger pin disengages from the push rod and allows the surgical element and the push rod to return to the retracted position. In some embodiments, the trigger pin is coupled to an actuator, such as a trigger or a plunger. The actuator is actuated in the distal direction to move the trigger pin distally over the ramp. In one configuration, the actuator is biased towards an initial position so that after the surgical element has been deployed and retracted, the actuator is biased back to the initial position and the apparatus is ready for repeat actuation. In another specific configuration, the actuator is moved along a longitudinal axis of motion which is parallel to the longitudinal axis of the push rod. In yet another specific configuration, the actuator is two pivotal handles. The handles are movable between an initial outwardly separated position and a closed position in which the handles are adjacent to the body. A user squeezes the handles to the closed position to move the surgical element to the deployed position. In most configurations, the handles are biased to the initial position, such that when the handles are released, the handles return to the initial position and the incisor is ready for repeat actuation.

In yet another embodiment, the incisor has an elongate rod with a surgical element disposed at the far end of the rod. A rod spring biases the rod and surgical

element in the retracted position. A hammer is positioned in the body, typically along an axis parallel with the push rod. Actuation of an actuator engages an angled cam surface against the hammer to move the hammer to compress a hammer spring. Once the trigger and cam surface move past the hammer, the cam surface disengages from the hammer so that the hammer spring can expand and push the hammer distally against the rod to move the surgical element to the deployed position. Because the rod and surgical element are biased in the retracted position by the rod spring, the surgical element is instantaneously pulled back to the retracted position.

In another aspect, the present invention provides methods of forming an incision in a tissue structure of a patient. In one method, a plunger is depressed substantially along a longitudinal axis of the device to move a surgical element from a retracted position to a deployed position. The surgical element is moved from the deployed position to the retracted position independently of further movement of the plunger. In most embodiments, the plunger is biased back to an undepressed position such that the plunger is ready for repeat actuation.

In yet another method, the present invention provides a method for inserting a cannula into a blood vessel. The method comprises positioning a tip of a device adjacent the blood vessel. An actuator is activated to move a surgical element from a retracted position to a deployed position. The surgical element is automatically moved from the deployed position to the retracted position while simultaneously inserting the cannula into the blood vessel. In most embodiments, the plunger is automatically returned to the undepressed position so that the plunger is ready for repeat actuation.

In yet another method, the present invention provides a method of creating an incision. The method comprises placing a distal tip of a device adjacent a vessel wall. An actuator is activated to compress a spring. The spring is expanded to deploy a surgical element to create an incision in a vessel. Thereafter, the surgical element is automatically retracted.

In yet another method, the present invention provides a method for occluding an aorta. A surgical element is deployed to create an opening in the aorta. The surgical element is automatically retracted and the cannula is inserted through the opening and into the aorta. The surgical element is withdrawn from the cannula and an aortic occlusion device is positioned in at least a portion of the aorta. In some methods, the aortic occlusion device includes an inflatable balloon which is expanded to occlude the aorta.

In still another aspect, the present invention provides an assembly for creating an incision in a blood vessel. The assembly includes a cannula having a lumen. An incisor having an automatically retracting surgical element is removably receivable within the lumen of the cannula. The cannula has a body and a push rod with a surgical element. An actuator is coupled to the push rod to move the surgical element between a retracted position and a deployed position. A fixed release mechanism is positioned within the body to disengage the push rod from the actuator to allow the push rod and surgical element to be biased from the deployed position to the retracted position.

In another embodiment, the assembly includes a cannula and an incisor having a hammer type assembly for retracting the surgical element. A hammer and hammer spring are positioned within the body and adjacent the push rod. A cam surface, typically coupled to an actuator, moves to compress the hammer and hammer spring. The cam surface is moved beyond the hammer and allows the hammer spring to expand so as to push the hammer distally against a push rod. The impulse from the hammer moves the surgical element from a retracted position to a deployed position. In most assemblies, the surgical element (and rod) are biased to the retracted position, such that the surgical element is immediately biased back to the retracted position.

In another embodiment, the present invention provides an assembly for treating the ascending aorta. The assembly includes a cannula having a lumen and an incisor having an automatically retracting surgical element. The incisor is removably received in the lumen of the catheter such that a surgical element is positioned near a distal end of the cannula to create an incision in the ascending aorta. An aortic occlusion device can be inserted through the lumen of the cannula and into the incision in the ascending aorta after the incisor has been removed from the cannula.

Other aspects, features, and advantages of the present invention will become apparent upon consideration of the following detailed description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an incisor within a cannula;

Fig 2 shows the cannula;

Fig. 3 shows an enlarged view of the distal end of the cannula of Fig. 2;

Fig. 4 is a plan view of a ring;

Fig. 5 is a side view of the ring of Fig. 4;

Fig. 6 show an aortic occluding device;

Fig. 7 shows the incisor disposed within the cannula and the incising element in a retracted position;

Fig. 8 shows the incisor disposed within the cannula and the incising element in a deployed position;

Fig. 9 shows the introduction of the cannula into the ascending aorta;

Fig. 10 shows the aortic occlusion device and cannula passing through an incision in the ascending aorta;

Fig. 11 is an exemplary embodiment of the incisor;

Fig. 12 is a cross-sectional view of the structure of the incisor of Fig. 11 with the plunger in an undepressed position and the incising element in a retracted position;

Fig. 13 is a cross-sectional view of the structure of the incisor of Fig. 11 with the plunger in a partially depressed position and the incising element in a deployed position;

Fig. 14 is a cross-sectional view of the structure of the incisor of Fig. 11 with the plunger in a fully depressed position and the incising element in the retracted position;

Fig. 15 is a cross-sectional view of another exemplary embodiment of an incisor with handles in an extended position and the incising element in a retracted position;

Fig. 16 is a cross-sectional view of the incisor of Fig. 15 with the handles in a closed position and the incising element in a deployed position;

Fig. 17A shows yet another embodiment of the incisor;

Fig. 17B shows the embodiment of 17B with the thumb switch in a proximal position and the surgical element in a retracted position;

Fig. 17C shows the thumb switch moving distally and the surgical element in a deployed position;

Fig. 17D shows the thumb switch in a distal position and the surgical element in the retracted position;

Fig. 18 shows a cross-sectional view of still another embodiment of the incisor of the present invention with the plunger in an undepressed position and the surgical element in a retracted position;

Fig. 19 shows a cross-sectional view of the incisor of Fig. 18 with the plunger in a partially depressed position and the surgical element in a retracted position;

Fig. 20 shows a cross-sectional view of the incisor of Fig. 18 with the plunger in a fully depressed position and the surgical element in a deployed position; and

Figs. 21A-21D illustrate a method of creating an incision in a vessel.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Apparatus and methods according to the present invention will generally be adapted for creating an incision within a target area of a body lumen, usually in the ascending artery or other coronary arteries.

In preferred embodiments, systems according to the present invention will comprise incisors, cannulas, and aortic occluding devices having elongate bodies adapted for introduction into the body. The dimensions and other physical characteristics of the catheter bodies will vary significantly depending on the procedure performed. In an exemplary case, the cannula, incisor, and aortic occluding device bodies are flexible to allow introduction from the outside the patient's cavity to the target site in the aorta or the heart. In other embodiments, any or all of the devices may be partially or entirely rigid.

Cannula bodies will typically be composed of a bicompatible organic polymer which is fabricated by conventional extrusion techniques. Suitable polymers can be found in commonly owned U.S. Patent No. 5,863,366, the full disclosure of which is incorporated herein by reference. Optionally, at least a portion of the cannula housing may be reinforced with braid, helical wires, axial filaments, or the like, in order to increase rotational strength, column strength, toughness, pushability, and the like. However, in some embodiments at least a portion of the lumen is not reinforced so that a clamp can be placed over the lumen to prevent the flow of body fluid (i.e. blood) up the lumen. A first arm of the cannula often has a keying feature, such as a colored marking, line, molded feature, or the like, which can promote proper alignment of the incisor with the cannula and with the aorta. In most embodiments, the combined weight of the cannula and incisor will be very light to facilitate easy manipulation and placement of the apparatus using one hand.

A surgical element, such as a cutting blade will be positioned at the distal end of the incisor. The cutting blades usually have at least two outwardly facing cutting edges and usually are formed from a metal such as stainless steel, but can also be formed from hard plastics, ceramics, or composites of two or more materials, which can be honed

or otherwise formed into the desired cutting edge. In the exemplary embodiments, the cutting blades have a width which is approximately equal to the inner diameter of the cannula. For example, when incising the ascending aorta, the blades will typically have a width between approximately 4 mm and 6 mm. The larger blades have been found create a clean incision while minimizing tearing in the artery wall. In most embodiments, the blade will extend approximately 2 mm - 6 mm past the distal tip of the incisor. Optionally, the cutting edges of the blades may be hardened, e.g. by chrome plating.

The incisor uses an actuator, plunger, trigger, or the like to actuate the deployment and retraction of the surgical element. In some embodiments, the trigger is movable along a parallel axis with the longitudinal axis of the cannula and incisor. Users can better control the deployment and retraction of the incising element when the trigger actuation direction is in the same direction as the deployment of the blade and insertion of the cannula. However, the present invention is not limited to such a configuration and in other embodiments alternative trigger configurations can be used.

While the remaining discussion will be directed toward creating an incision in the ascending aorta, it will be appreciated that the concepts of the present invention can be used to create an incision or perforation in a variety of other organs, vessels, and tissue structures.

Referring to Fig. 1, a system 10 of the present invention comprises a cannula 12 and an incisor 14. As illustrated in Figs. 1 and 2, the cannula 12 is typically used to return oxygenated blood to the patient when the patient's heart is arrested. The cannula comprises a lumen 16 having a proximal end 18 and a distal end 20. The lumen 16 has a reinforced section 21. The reinforced section 21 is preferably formed in the manner described in U.S. Patent No. 5,863,366, which was previously incorporated by reference. A Y-arm connector 22 having a first arm 24 and a second arm 26 is fluidly coupled to the proximal end of the elongate lumen 16. The first arm 24 has an opening which can receive the shaft of the incisor 14. The second arm 26 has a hemostasis valve 27. The hemostasis valve 27 can be any of a variety of known hemostasis valves, but is preferably a Thouy-Borst valve. Referring now to Fig. 3, the distal end 20 of the cannula is angled and has a distal opening 28 and two side ports 30 for infusing oxygenated blood into the vasculature of the patient. Optionally, radiopaque markers 32 are provided at the distal end for visualization using fluoroscopy. As shown most clearly in Figs. 4 and 5, a ring 34 is attached to the distal end 20 of the cannula 12. The ring 34 limits the depth of insertion of the cannula 12 into the vessel, stabilizes the cannula 12, and receives purse-

string sutures within slots 36 to provide hemostasis around the cannula 12 when the cannula 12 is positioned in the vessel.

The system of the present invention includes, in a preferred embodiment, an aortic occlusion device for internal occlusion of the aorta. Referring to Fig. 6, one embodiment of an aortic occlusion device 13 is shown. The aortic occlusion device 13 has an occluding member 15 configured to occlude a patient's ascending aorta. The occluding member is preferably a balloon but may also be a mechanically actuated member. The aortic occlusion device 13 has an inflation lumen 17 for inflating the occluding member 15, a pressure lumen 19 for measuring pressure in the ascending aorta, and a lumen 21 for delivering cardioplegic fluid and/or venting the ascending aorta. The aortic occlusion device 13 can be manufactured in a manner such as extrusion, but is preferably manufactured and used as described in U.S. Patent Application Serial No. 08/782,113, filed January 13, 1997, the full disclosure which is incorporated herein by reference.

The aortic occlusion device 13 is preferably substantially straight in an unbiased position, however, the aortic occlusion device may also have a shaped end. For example, the aortic occlusion device can have a curved or an L-shaped end which facilitates positioning the occluding member 15 in the ascending aorta depending upon the surgical approach. The aortic occlusion device is preferably flexible so that it can be bent as necessary without kinking. A more complete discussion of the aortic occlusion device can be found in U.S. Patent Application Serial No. 09/235,043, filed January 21, 1999, the full disclosure of which is incorporated herein by reference. In use, the aortic occlusion device 13 can be introduced into the patient through the cannula 12. The cannula is positioned in a patient's ascending aorta with the aortic occlusion device 13 passing through the hemostasis valve 27 (Fig. 10).

Referring now to Figs. 7-8, an introducing incisor 14 is positioned in the cannula 12 to create an incision so that the cannula 12 and aortic occlusion device 13 can be introduced into the vessel. The incisor has a connector hub 38 which is received by the first arm 24 of the cannula 12 to provide a sealed connection between the incisor 14 and the cannula 12. The incisor 14 has an incising element 40 to create an incision in the wall of the vessel. The incising element 40 is attached to a push rod (not shown) which is coupled to a plunger 42 for moving the incising element 40 between the retracted position (Fig. 7) and the exposed position (Fig. 8). The incising element 40 is preferably biased in the retracted position and is only exposed when the plunger 42 is depressed by the user.

Generally, purse string sutures 39 can be sewn in the ascending aorta prior to advancing the cannula and incisor. The purse strings can provide hemostasis around the cannula (after it has been advanced into the aorta). The cannula and incisor are then moved adjacent an outer wall of the aorta. In some embodiments, the distal tip 56 of the incisor 14 can include traction features 57, such as a roughened surface, protrusions, or the like, which help maintain the distal tip within the purse string sutures (Fig. 11). Light pressure is applied to the incisor to create a dimple or indentation in the aorta so that the distal tip remains in a centered position within the purse strings when the incising element is advanced into aorta wall. After the incision is created, the cannula and incisor are advanced through the incision and into the aorta. The incising element is retracted as the trigger is advanced and the purse string sutures are tensioned around the cannula. The radiopaque marker at the cannula tip may be viewed under fluoroscopy and the cannula manipulated until the angled tip is directed toward the aortic valve (Fig. 9). The aortic occlusion device is then passed through the hemostasis valve and advanced until the occluding member is positioned in the ascending aorta. Delivery of oxygenated blood, occlusion of the ascending aorta, and delivery of cardioplegic fluid is then performed in the manner described in U.S. Patent No. 5,584,803, the full disclosure of which is incorporated herein by reference.

As shown in Fig. 10, the lumen 21 of the occlusion device is coupled to a source of cardioplegic fluid 43, the inflation lumen 15 is coupled to a source of inflation fluid 47, and the pressure lumen 19 is coupled to the pressure monitor 51 for measuring pressure in the ascending aorta. The lumen can also be coupled to a vacuum source 53 for venting the ascending aorta.

The first arm 24 of the cannula is coupled to a source of oxygenated blood 55 so that blood is delivered through the lumen of the cannula with the blood passing through the annular region between the cannula 12 and the aortic occlusion device.

Figs. 11 and 12 illustrate an exemplary embodiment of an incisor of the present invention. The incisor 14 includes a push rod 48 having a proximal end 50 and a distal end 52. The push rod is rigid enough to transmit a compressive force between the proximal and distal ends, but preferably is still flexible enough to advance through a curved cannula. A surgical element 40 such as a blade or incising element is attached to the distal end of the push rod 48, while the proximal end of the push rod has a surface or enlarged push cap which can be engaged by at least one plunger finger (described in more detail herein below). An elongate housing 54 having a tapered or angled distal tip

surrounds the push rod and incising element. An opening or slot within the angled distal tip 56 allows the surgical element to move from a retracted position to a deployed position. A body 58 having an opening which receives the proximal end of the push rod 50 is attached to the proximal end of the elongate housing 54. A retraction spring 60 positioned within the body 58 is coupled to the proximal end of the push rod 50 to bias the push rod 48 and surgical element 40 in the retracted position. A movable actuator 42, such as a plunger or trigger, releasably engages the proximal surface of the push rod. As will be described in more detail below, a ramp or cam surface 70 is disposed within a distal end of the body 58 to disengage the fingers 64 from the push rod as the plunger 42 moves toward the fully depressed position. Optionally, a set screw 68 can be attached to the plunger 42 to prevent the plunger 42 from rotating. Additionally, the set screw 68 can act as an indicator to inform the user how far the incising element has been deployed.

As illustrated in Fig. 11, in some configurations the body has two finger grips 72 which extend radially from the body 58 and a plunger 42 that extends proximally through an opening in the body 58. The incisor is grasped with the user's fingers like a hypodermic needle and is actuated with either the thumb or the palm of the hand. Such a configuration allows the user to manipulate the incisor with only one hand, while providing the user with enhanced control of the incisor.

As shown in Fig. 12 the plunger is maintained in the undepressed position by a plunger return spring 66, and the blade 40 is maintained in the retracted position within the distal tip 56 by the rod retraction spring 60. In the initial undepressed position the plunger finger(s) 64 may or may not contact the proximal end of the push rod 50. As shown by the arrow in Fig. 13, the plunger is advanced by pushing on the engagement surface 62 to overcome the resistance of the return spring 66 and retraction spring 60. Protrusions 63 on the plunger finger(s) 64 contact and begin to push on the proximal surface 50 of the push rod. As the plunger 42 is advanced, the push rod 48 and surgical element 40 are advanced with the plunger. In most embodiments the push rod 48 and blade 40 are advanced at a 1:1 rate with the plunger 42, however, in other embodiments, the ratio can be modified. As the plunger nears the end of its path, a surface of the plunger finger(s) 64 engage the ramps 70. As the fingers advance over the ramps, the fingers 64 are urged radially outward away from the proximal end of the push rod. When the push rod 48 has been advanced to a fully deployed position, the ramp disengages the plunger finger(s) 64 from the proximal end of the push rod (Fig. 14). The retraction spring 60 then urges the push rod 48 (and surgical element 40) back to its initial, retracted

position. In most embodiments, the release of the push rod will create an audible click to inform the user that the surgical element has been retracted.

As the plunger is released, the return spring 66 biases the plunger 42 back to the initial undepressed position (Fig. 11). As the plunger fingers 64 pass by the proximal surface of the push rod 48, the resilient spring force contained in the flexed plunger fingers bias the fingers radially inward to the initial position and into engagement (or near engagement) with the proximal end 50 of the push rod. At this position, the plunger and push rod are positioned for additional repeat actuation. Optionally, a locking mechanism may be provided to lock the plunger after a single actuation to prevent inadvertent repeat actuation.

Figs. 15 to 16 illustrate another exemplary embodiment of the incisor 14A having an automatically retracting surgical element. The incisor 14A has a push rod 74 with a proximal end 76 and a distal end 78. An incising element 80 is attached to the distal end of the push rod and a return plate 82 is coupled to the proximal end of the push rod. Return plate 82 is movable distally and proximally relative to body 87. An aperture 84 in the return plate 82 is sized to releasably receive a trigger pin 86. In most configurations, the trigger pin 86 is biased with a compression spring 90 into the aperture 84 of the return plate 82. In most embodiments, handles 88 are pivotally coupled to body 87 and are linked to return plate 82 through the trigger pin. A ramp or cam surface 92 is disposed on the body adjacent the return plate 82 so that actuation of the handle 88 and trigger pin 86 move the return plate, push rod, and surgical element from the retracted position to the deployed position.

In use, a user actuates the handle (or actuator) 88 to move the return plate 82, push rod 74 and incising element 80 distally, thereby moving trigger pin 86 up the ramp 92. As the trigger pin 86 moves up the ramp 92, the trigger pin 86 begins to move out of the aperture 84 in the return plate 82. When the trigger pin 86 reaches the top of the ramp, the trigger pin is urged out of the aperture and disengages from the return plate 82. A return spring 94 then urges the return plate 82, push rod 74, and surgical element 80 back to the retracted position. When the user releases the handle 88, a trigger return spring 96 or an equivalent, urges the actuator and trigger pin back to its initial position. Because the trigger pin 86 is biased toward the return plate 82, the trigger pin is urged back into the aperture 84 and the device is ready for actuation.

In a specific configuration, the actuator comprises two pivotal handles 88A, 88B which are movable between an extended position in which the handles are

outwardly separated and a closed position in which the handles are adjacent the body. Handle springs 96 bias the handles in the extended position and automatically return the handles to the extended position after each actuation. When the handles are squeezed together, return plate 82 is advanced distally and the trigger pin 86 is moved up the ramp, as described above.

As illustrated in Figs. 17A to 17D, in another specific configuration of the incisor 14B, the trigger comprises a linearly actuated thumb trigger 88C which moves along an axis which is substantially parallel to the longitudinal axis of the blade rod. Actuation of the trigger in a distal direction moves the surgical element distally. The distal motion of the trigger has been found to be more natural since the distal movement of the trigger coincides with the distal advancement of the blade and the distal advancement of the cannula through the incision.

As shown in Figs. 17A and 17B, the incisor 14B has a push rod 74 with a proximal end 76 and a distal end 78. An surgical element 80 is attached to the distal end of the push rod and a return plate 82 is coupled to the proximal end of the push rod. Return plate 82 is movable distally and proximally relative to body 87. An aperture 84 in the return plate 82 is sized to releasably receive a pin 86. In most configurations, the pin 86 is biased with a compression spring 90 into the aperture 84 of the return plate 82. Thumb switch 88C is slidably attached to body 87 and is coupled to return plate 82 through the pin 86. As shown in Fig. 17C, a ramp or cam surface 92 is disposed on the body adjacent the return plate 82 such that actuation of the thumb switch 88 and trigger pin 86 move the return plate 82, push rod 74, and surgical element 80 from the retracted position to the deployed position. As the pin 86 nears its most distal point, the ramp engages the pin and the pin 86 begins to move out of the aperture 84 (Fig. 17C). When the pin 86 reaches the top of the ramp, the pin is urged completely out of the aperture. The pin 86 disengages from the return plate 82 and a return spring 94 urges the return plate 82, push rod 74, and surgical element 80 back to the retracted position. When the user releases the thumb switch 88C, a return spring 96 or an equivalent, urges the thumb switch 88C and pin back to their initial position. Because the pin 86 is biased by spring 90 toward the return plate 82, the pin is urged back into the aperture 84 and the incisor is ready for repeat actuation.

Referring now to Figs. 18-20, yet another incisor 14C is shown. The incisor shown comprises a mechanism which instantaneously advances and retracts the surgical element. The incisor 14C has a distal surgical element 98 coupled to a push rod

100. Similar to above, the surgical element 98 and the push rod 100 are biased by a push rod spring 102 in a retracted position within an elongate housing 104. A hammer 106 having a protrusion 108 is movable within housing 104 along substantially the same axis as the push rod 100, although unconnected with the push rod. A hammer compression spring 110 is disposed proximal of the hammer within housing 104 to provide the mechanism for actuating the hammer. A trigger 112 comprising a cam or ramp 114 is movable in a transverse direction relative to hammer 106 and is urged outwardly by a trigger spring 116 (Fig. 18). Angled surface 115 of the cam engages the protrusion 108 and forces the hammer 106 proximally against the compression spring 110 (Fig. 19). As the trigger 112 is advanced further, the cam 114 advances past the protrusion 108 and allows the hammer spring 110 to expand and force the hammer 106 distally so as to strike the proximal end of push rod 100. The impulse from the hammer 106 moves the push rod 100 and the surgical element 98 (i.e., a blade) instantaneously from its retracted position to a deployed position (Fig. 20). Because the push rod 100 and surgical element 98 are spring loaded to the retracted position, the push rod 100 and surgical element 98 are immediately urged from the deployed position back to the retracted position. The stiffness of springs 102 and 110 are selected such that the force of hammer 106 is sufficient to overcome the resistive force of spring 102 to drive rod 100 distally.

Use of the cannula, incisor and aortic occlusion device will now be described with reference to Figs 21A-21D. The description below is applicable to all the incisors 14, 14A, 14B, 14C described herein. Referring again to Fig. 9, before introduction of the cannula, a rib retractor 115 or other device can be used to form an opening in an intercostal space such as the fourth intercostal space. The opening through the intercostal space is used for access to perform a surgical procedure such as a valve repair or replacement or coronary bypass graft. The opening also provides direct access to the ascending aorta for control of the ascending aorta and to place purse string sutures in the aorta. The surgeon then places two purse-string sutures 39 around the site. The ends of the purse-string sutures are passed through tourniquet tubing which is used to tension the purse-string sutures. The purse string sutures are then passed through the slots 36 in the ring 34.

An incision is also created in the first or second intercostal space in which a trocar is positioned. The cannula 121 and incisor assembly 120 are then introduced through the trocar and advanced to the surface of the aorta with the incisor 119 positioned in the lumen 118 of the cannula 121. As illustrated in Fig. 21A, the cannula/incisor

assembly are then advanced into contact with the aorta at the site now surrounded by the purse-string sutures. A light pressure can be applied with the traction features 123 of the distal tip 122 against the aorta to create dimples or indentations so as to help center the surgical element within the purse strings. The user then depresses the plunger to move the push rod 126 and the incising element 124 to a deployed position (Fig. 21B). As shown in Figs. 21C and 21D, the incising element creates an incision in the wall of the vessel, and the incisor and the cannula tip are pushed through the wall until the ring contacts the adventitial surface of the vessel. As the trigger is further depressed, the incising element is automatically released and returns back to the retracted position. Once the cannula tip has been inserted into the blood vessel, the incisor can be removed and the aortic occluding device can be inserted through the hemostasis valve in the first am and down the cannula (Fig. 10).

The systems and methods described above have been described in relation to the ascending aorta for clarity of understanding. The devices and methods of the present invention may have application in other parts of the aorta or heart and in other vessels and organs of the body. As changes and modifications will be obvious to those of skill in the art, the scope of the invention is limited solely by the following claims.

WHAT IS CLAIMED IS:

1. An apparatus for creating a vascular incision comprising:

a body;

a rod movable relative to the body and having a proximal end and a distal end;

a surgical element disposed at the distal end of the rod, wherein the rod and surgical element are movable between a retracted position and a deployed position, wherein the rod and surgical element are biased in the retracted position;

an actuator coupled to at least one finger which engages the proximal end of the rod, wherein activation of the actuator advances the surgical element from the retracted position to the deployed position; and

a ramp on the body to engage the finger as the rod and surgical element move to the deployed position, wherein the ramp disengages the finger from the proximal end of the rod to allow the surgical element to move to the retracted position.

2. The apparatus of claim 1 further comprising a return spring, wherein the actuator is movable between an undepressed position and a depressed position, wherein the return spring biases the actuator to the undepressed position.

3. The apparatus of claim 2 wherein the actuator defines a longitudinal axis and the rod defines a longitudinal axis, wherein the longitudinal axis of the actuator is substantially aligned with the longitudinal axis of the rod.

4. The apparatus of claim 1 wherein the actuator is coupled to multiple fingers which engage the rod.

5. The apparatus of claim 1 wherein the proximal end of the rod comprises an enlarged push rod cap.

6. The apparatus of claim 5 wherein the finger comprises a protrusion which engages the push rod cap.

7. The apparatus of claim 1 wherein the actuator is adapted to be engaged by a user's thumb or palm.

8. The apparatus of claim 1 wherein the body comprises finger grips adapted to be held by the user's fingers.

9. The apparatus of claim 1 wherein the finger disengages from the rod when the rod and surgical element have been advanced to a fully deployed position.

10. The apparatus of claim 1 wherein the finger is flexible and is resiliently biased radially inward towards the proximal end of the rod.

11. The apparatus of claim 1 wherein the disengagement of the finger from the rod creates an audible click.

12. The apparatus of claim 1 wherein the ramp forces the finger radially outward away from the proximal end of the rod.

13. The apparatus of claim 1 wherein the surgical element is a blade.

14. The apparatus of claim 13 wherein the blade has a width between approximately 4 mm and 6 mm.

15. The apparatus of claim 13 wherein a leading edge of the blade has two outwardly facing edges.

16. The apparatus of claim 13 wherein the rod is advanced at a 1:1 rate with the actuator.

17. The apparatus of claim 1 further comprising an elongate housing which extends distally from the body to encase the rod and surgical element.

18. The apparatus of claim 17 wherein the elongate housing and rod are flexible.

19. The apparatus of claim 17 wherein the elongate housing comprises a tapered distal tip having an opening to allow the surgical element to move between the retracted position and the deployed position.

20. The apparatus of claim 17 further comprising a cannula removably coupled to the elongate housing, the rod extending through the cannula.

21. The apparatus of claim 20 wherein the cannula comprises a keying element to align the cannula in a predetermined orientation relative to the surgical element.

22. The apparatus of claim 21 wherein the combination of the body, rod, surgical element, actuator, ramp, and rod spring are lighter than the cannula.

23. An automatically retracting incisor comprising:

a housing;

a push rod having a proximal end and a distal end, wherein the push rod is movable between a retracted position and a deployed position, the push rod coupled to the housing and biased toward the retracted position;

a surgical element disposed at the distal end of the push rod;

a trigger pin releasably engaging the proximal end of the push rod; and

a ramp on the housing engaging the trigger pin, wherein movement of the trigger pin moves the push rod and the surgical element from the retracted position towards the deployed position such that the trigger pin slides along the ramp, wherein the trigger pin reaches a top of the ramp and the trigger pin disengages from the push rod to allow the surgical element and push rod to return to the retracted position.

24. The automatically retracting incisor of claim 23 wherein the trigger pin is coupled to an actuator, wherein the actuator is movable between an initial position and an actuated position.

25. The automatically retracting incisor of claim 24 wherein the actuator comprises two handles.

26. The automatically retracting incisor of claim 25 wherein the handles are pivotally coupled to the body.

27. The automatically retracting incisor of claim 26 wherein the handles in the initial position are outwardly separated from the body and the handles in the actuated position are adjacent to the body.

28. The automatically retracting incisor of claim 27 wherein the handles in the actuated position move the surgical element to the deployed position.

29. The automatically retracting incisor of claim 27 wherein the handles are biased towards the initial position.

30. The automatically retracting incisor of claim 24 wherein the push rod defines a longitudinal axis and the actuator defines a longitudinal axis of motion, wherein the longitudinal axis of motion of the actuator is parallel to the longitudinal axis of the push rod.

31. The automatically retracting incisor of claim 24 wherein the actuated position is distal of the initial position.

32. The automatically retracting incisor of claim 24 wherein the actuator comprises a thumb switch slidably coupled to the body.

33. The automatically retracting incisor of claim 24 wherein the actuator is biased to the initial position.

34. The automatically retracting incisor of claim 23 wherein the trigger pin is removably received in an aperture in the push rod.

35. The automatically retracting incisor of claim 34 wherein the trigger pin is biased into the aperture and is urged out of the aperture by the ramp.

36. The automatically retracting incisor of claim 23 wherein the surgical element is a blade.

37. The automatically retracting incisor of claim 23 wherein movement of the surgical element from the deployed position to the retracted position makes an audible sound.

38 The automatically retracting incisor of claim 23 wherein the push rod and surgical element are encased by an elongate housing, the elongate housing being attached to the body.

39. An incisor comprising:

a body;

an elongate rod coupled to the body, the elongate rod comprising a proximal end and a distal end;

a surgical element positioned at the distal end of the rod, wherein the surgical element and rod are movable between a retracted position and a deployed position, the rod and surgical element being biased to the retracted position;

a hammer positioned in the body;

a hammer spring in engagement with the hammer;

an actuator coupled to a cam having a surface which engages the hammer, wherein movement of the actuator from an initial position to an actuated position moves the hammer to compress the hammer spring, wherein the cam disengages from the hammer, to allow the hammer spring to expand and push the hammer distally against the push rod so as to move the surgical element to the deployed position.

40. The incisor of claim 39 further comprising a actuator spring which biases the actuator in the initial position.

41. The incisor of claim 39 wherein the surgical element and rod are biased to the retracted position by a rod spring, the rod spring immediately biasing the surgical element and rod from the deployed position to the retracted position.

42. The incisor of claim 39 wherein the hammer is decoupled from the elongate rod.

43. A method of deploying and retracting a surgical element, the method comprising:

depressing a plunger substantially along a longitudinal axis of the device to move the surgical element from a retracted position to a deployed position; and

moving the surgical element from the deployed position to the retracted position independently of further movement of the plunger.

44. The method of claim 43 further comprising biasing the plunger to an undepressed position.

45. The method of claim 43 comprising informing the user that the surgical element has been retracted.

46. The method of claim 45 wherein the informing step is carried out by making an audible click.

47. The method of claim 43 further comprising positioning the surgical element through a cannula.

48. The method of claim 43 wherein an incision in the tissue structure is created during the depressing step.

49. The method of claim 48 comprising advancing a cannula through the incision before removing the surgical element from the incision.

50. The method of claim 49 wherein the plunger is depressed in the same direction as the cannula is advanced.

51. The method of claim 49 wherein the depressing step and the advancing step are carried out substantially simultaneously.

52. The method of claim 43 further comprising releasing the plunger to move the plunger from a depressed position to an undepressed position.

53. The method of claim 43 wherein the moving step is carried out by disengaging the plunger from a rod attached to the surgical element.

54. The method of claim 43 wherein the surgical element is a blade.

55. A method of inserting a cannula into a blood vessel comprising:
positioning an incisor adjacent the blood vessel;
activating an actuator to move a surgical element from a retracted position to a deployed position to create an incision in the blood vessel wall; and
automatically moving the surgical element from the deployed position to the retracted position while simultaneously inserting the cannula into the blood vessel.

56. The method of claim 55 further comprising maintaining the position of the incisor within the cannula during the moving step.

57. The method of claim 55 further comprising automatically returning the actuator to an initial position.

58. The method of claim 55 wherein the actuator is coupled to the surgical element through a rod, wherein the moving step is carried out by biasing the rod to the retracted position.

59. The method of claim 55 wherein the actuator is advanced distally to move the surgical element to the retracted position.

60. The method of claim 55 wherein the cannula is inserted in the same direction as the actuator is advanced.

61. The method of claim 55 wherein the activating step is carried out by squeezing two handles together.

62. A method of creating an incision comprising:

placing a distal tip of a device adjacent a vessel wall;

activating an actuator to compress a spring;

expanding the spring to deploy a surgical instrument to create an incision in the vessel wall; and

automatically retracting the surgical element.

63. The method of claim 62 wherein the expanding step is performed independently of further activating of the actuator.

64. The method of claim 62 wherein during the activating step the actuator engages a protrusion on a hammer with a cam surface.

65. The method of claim 64 wherein the expanding step is carried out by moving the cam surface beyond the protrusion on the hammer such that the hammer is released and the spring moves the hammer to deploy the surgical element.

66. The method of claim 62 further comprising biasing the actuator to an initial position, wherein the actuator in the initial position is ready for repeat actuation.

67. An assembly for creating an incision in a blood vessel, the assembly comprising:

a cannula having a lumen;

an incisor having an automatically retracting surgical element, the incisor being removably receivable within the lumen of the cannula, the incisor comprising:

a body;

a push rod coupled to the surgical element, the push rod and surgical element being movable relative to the body between a retracted position and a deployed position, wherein the push rod and surgical element are biased in the retracted position;

an actuator coupled to the push rod, the actuator facilitates the movement of the push rod and surgical element from the retracted position to the deployed position;

a fixed release mechanism positioned on the body, wherein movement of the actuator to a first position moves the push rod and surgical element from the retracted position to the deployed position so as to create an incision in the blood vessel, wherein activation of the actuator to a second position causes the fixed release mechanism to disengage the push rod from the actuator and allow the push rod and surgical element to be biased back to the retracted position.

68. The assembly of claim 67 wherein the actuator is biased back to an initial position.

69. The assembly of claim 67 wherein the actuator comprises handles pivotally connected to the body, wherein the handles in the first position are outwardly separated from the body and the handles in the second position are adjacent to the body.

70. The assembly of claim 67 wherein the incisor comprises finger grips adapted to be held by a user's fingers.

71. The assembly of claim 67 wherein the actuator comprises a thumb switch.

72. The assembly of claim 67 wherein the actuator is coupled to the push rod with at least one flexible finger.

73. The assembly of claim 67 wherein a trigger pin on the actuator releasably engages an aperture on the proximal end of the push rod

74. An assembly for creating an incision in a blood vessel, the assembly comprising:

a cannula having a lumen;

an incisor having an automatically retracting surgical element, the incisor being removably receivable within the lumen of the cannula, the incisor comprising:

a body;

a rod having the surgical element at a distal end, wherein the surgical element and rod are movable between a retracted position and a deployed position, the rod and surgical element being biased to the retracted position;

a hammer coupled to the body;

a hammer spring in engagement with the hammer;

a movable cam having a surface which engages the hammer, wherein movement of the cam surface from an initial position to an actuated position moves the hammer to compress the hammer spring, wherein disengagement of the cam surface from the hammer causes the hammer spring to expand and push the hammer distally against the rod to move the surgical element to the deployed position.

75. A method of occluding an aorta comprising:

deploying a surgical element to create an opening in the aorta;

automatically retracting the surgical element;

inserting the cannula through the opening and into the aorta;

withdrawing the surgical element from the cannula; and

positioning an aortic occlusion device in at least a portion of the aorta.

76. The method of claim 75 wherein the retracting step and inserting step are performed substantially simultaneously.

77. The method of claim 75 wherein the surgical element is moved from the retracted position to the deployed position through activation of an actuator.

78. The method of claim 77 wherein the retracting step is carried out independently of further activation of the actuator.

79. The method of claim 75 wherein the cannula is inserted into the aorta before removing the surgical element from the incision.

80. The method of claim 75 further comprising expanding an occluding member to occlude aorta.

81. An assembly for treating the ascending aorta comprising:

a cannula having a lumen;

an incisor having an automatically retracting surgical element, the incisor being removably received in the lumen of the cannula, wherein the surgical element is positioned near a distal end of the cannula to create an incision in the ascending aorta; and

an aortic occlusion device insertable through the lumen of the cannula and into the incision in the ascending aorta after the incisor has been removed from the cannula.

82. The assembly of claim 81 wherein the cannula and incisor are simultaneously inserted through the incision.

83. The assembly of claim 82 wherein the aortic occlusion device comprises at least one lumen and an occluding member.

84. The assembly of claim 83 wherein the occluding member comprises a balloon.

85. The assembly of claim 81 wherein the surgical element is attached to a push rod, wherein an actuator facilitates movement of the push rod and surgical element from a retracted position and a deployed position.

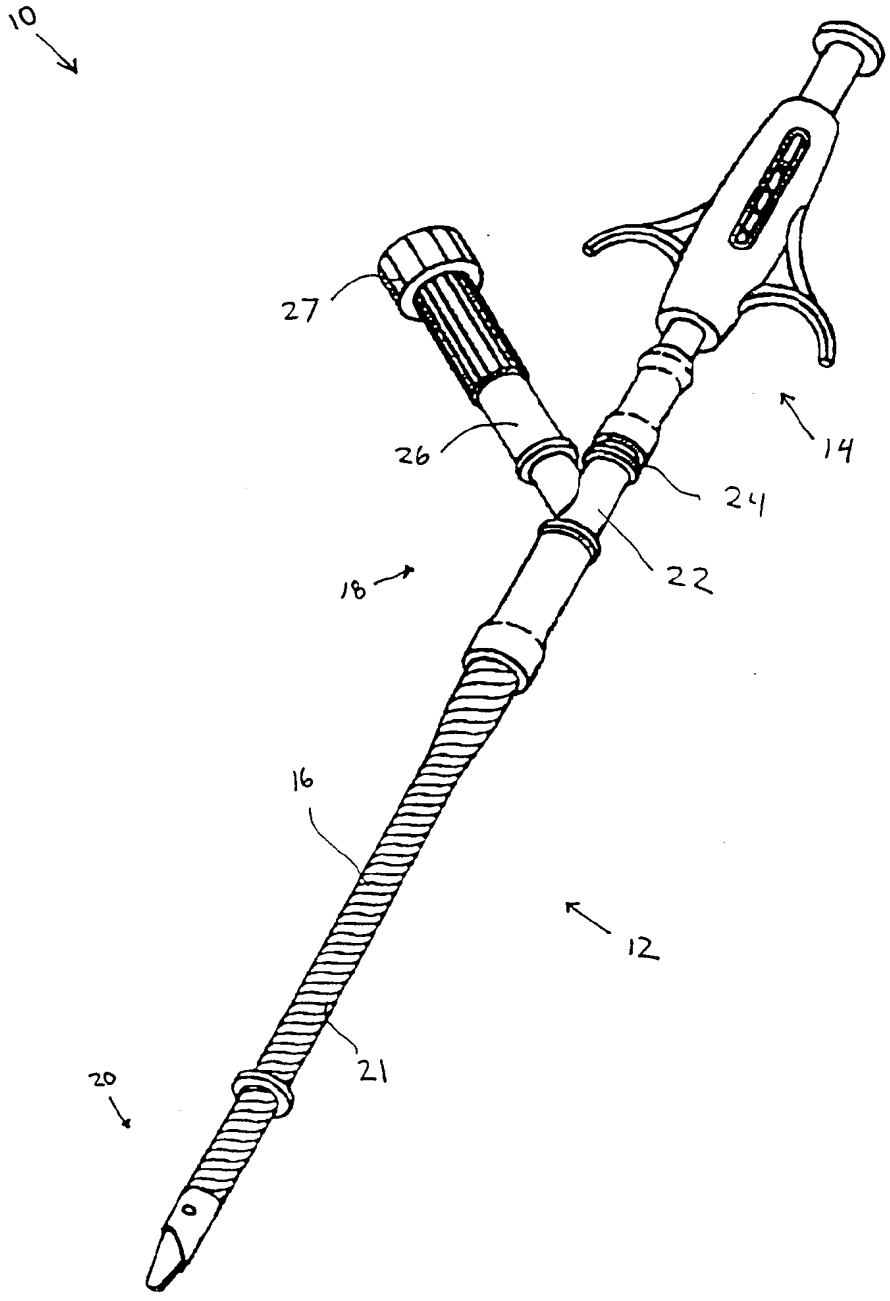


FIG. 1

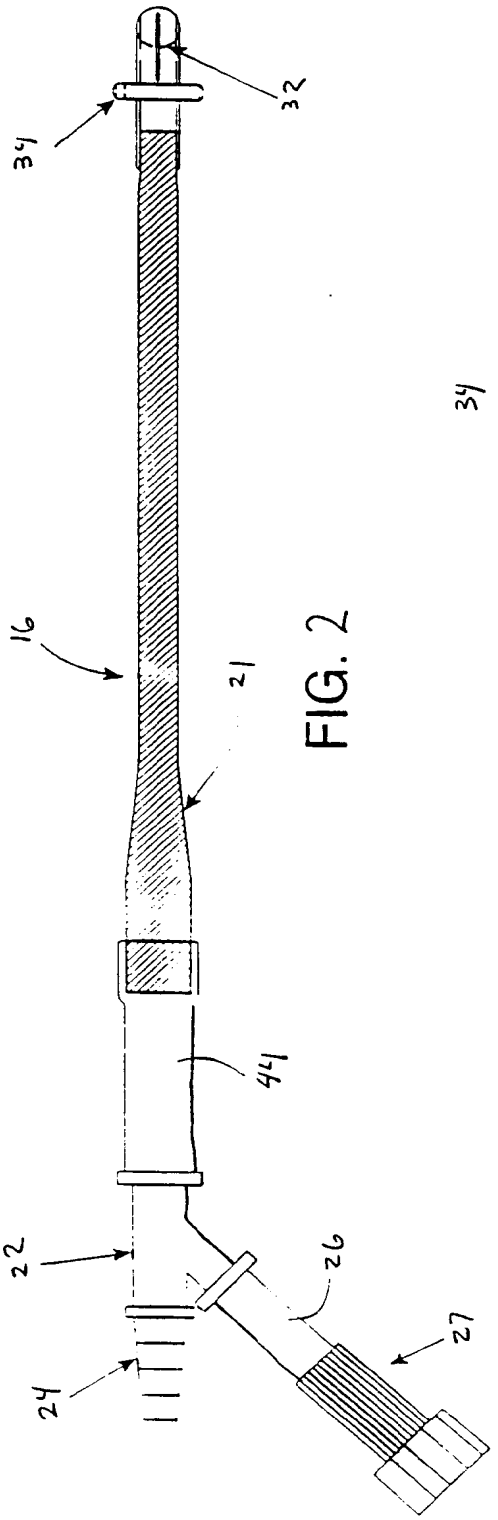


FIG. 2

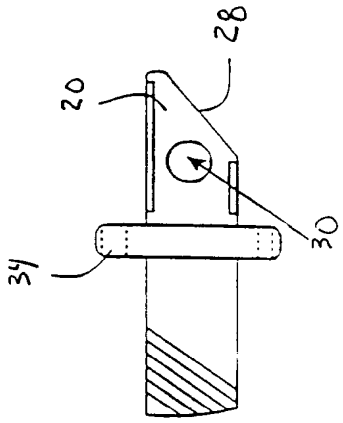


FIG. 3

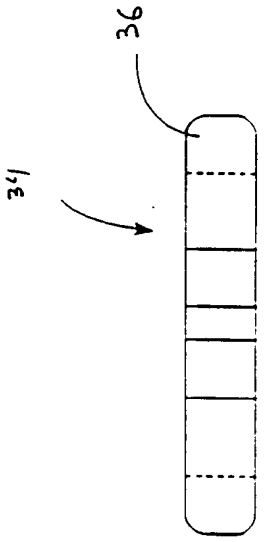


FIG. 5

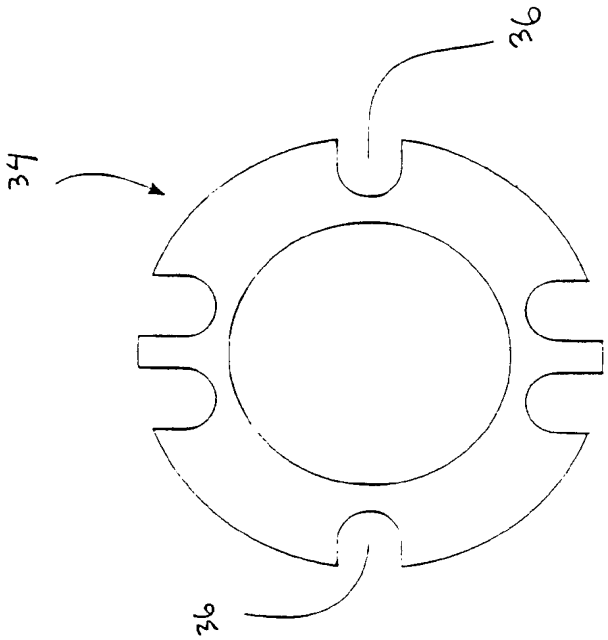


FIG. 4

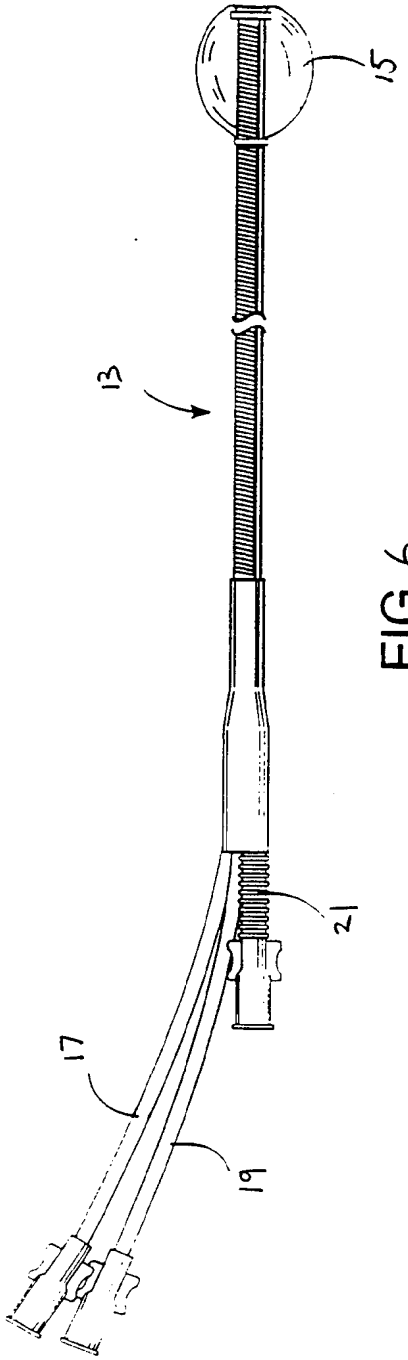


FIG.6

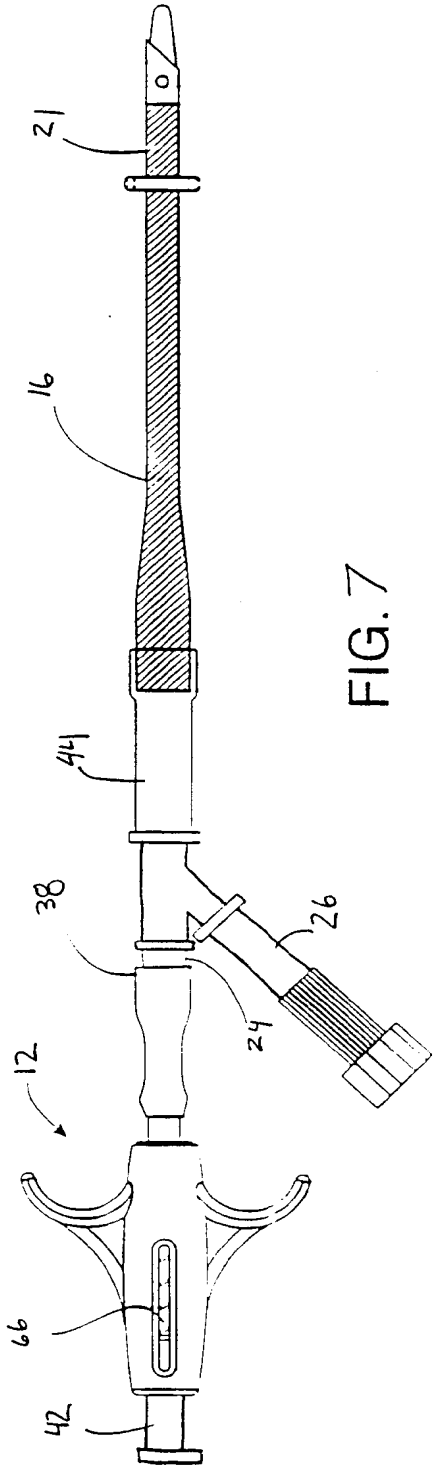
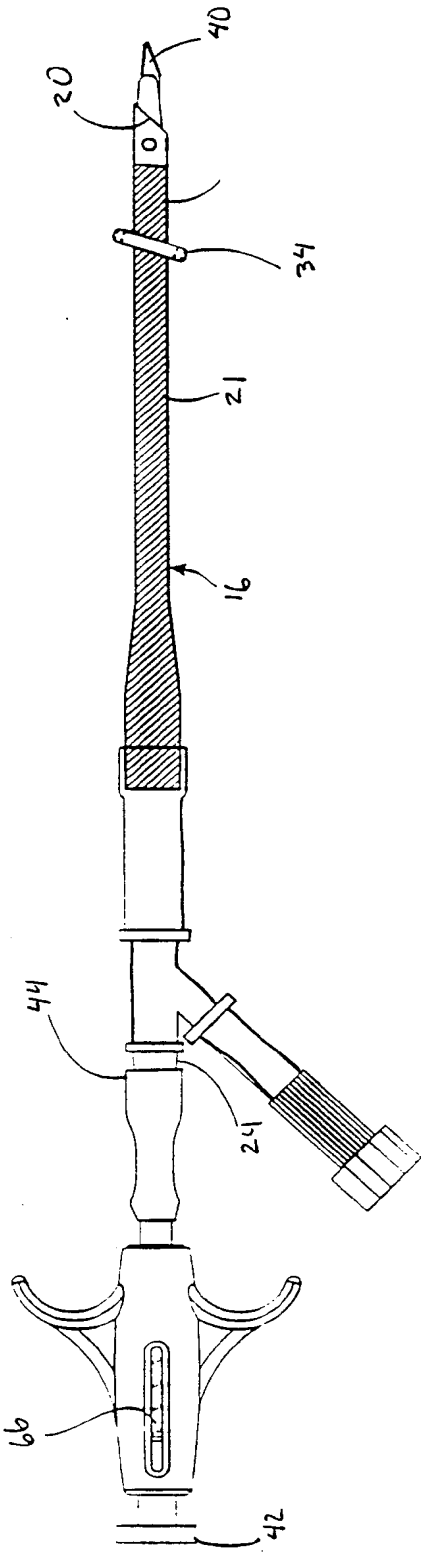


FIG. 7

FIG. 8



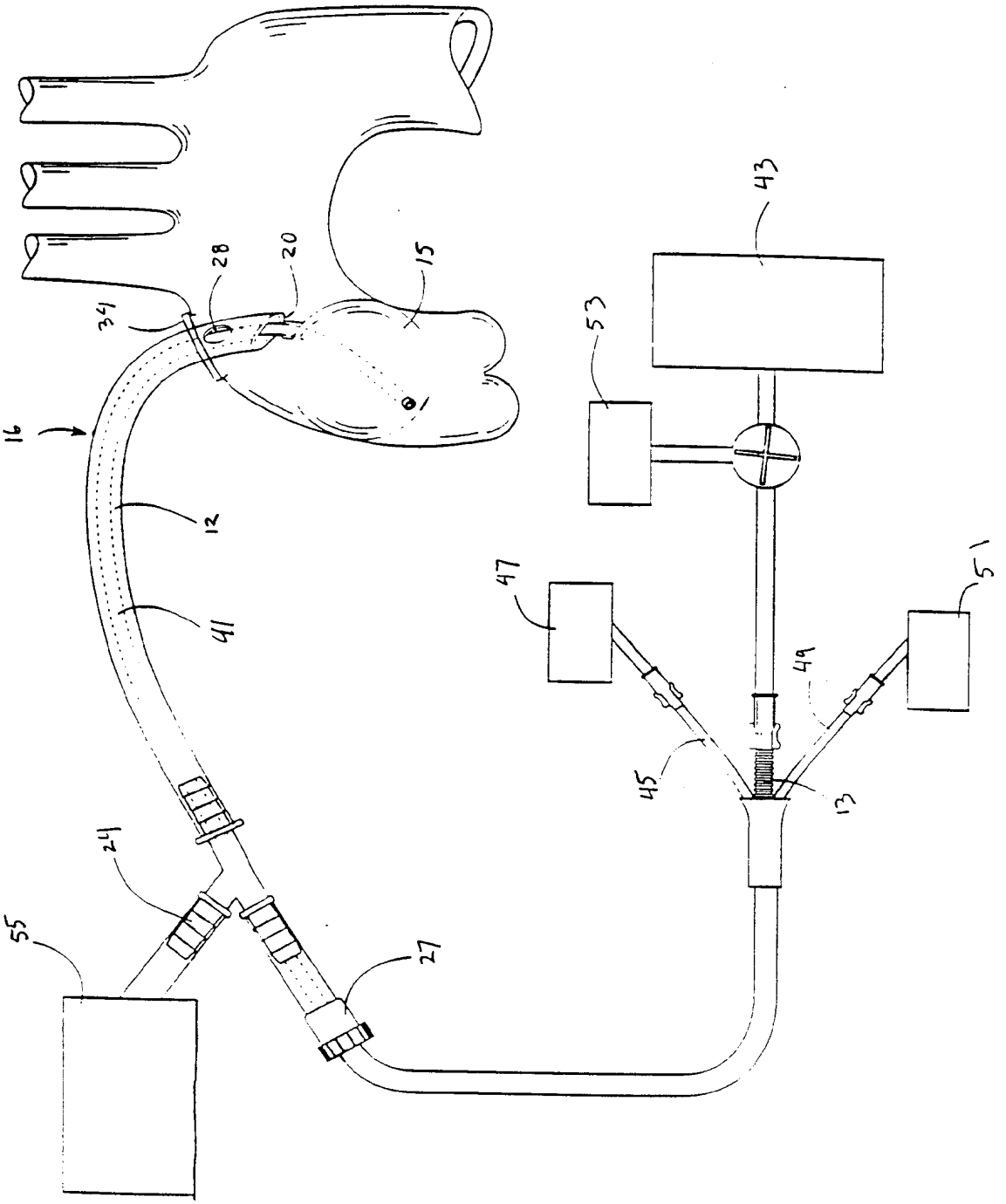


FIG.10

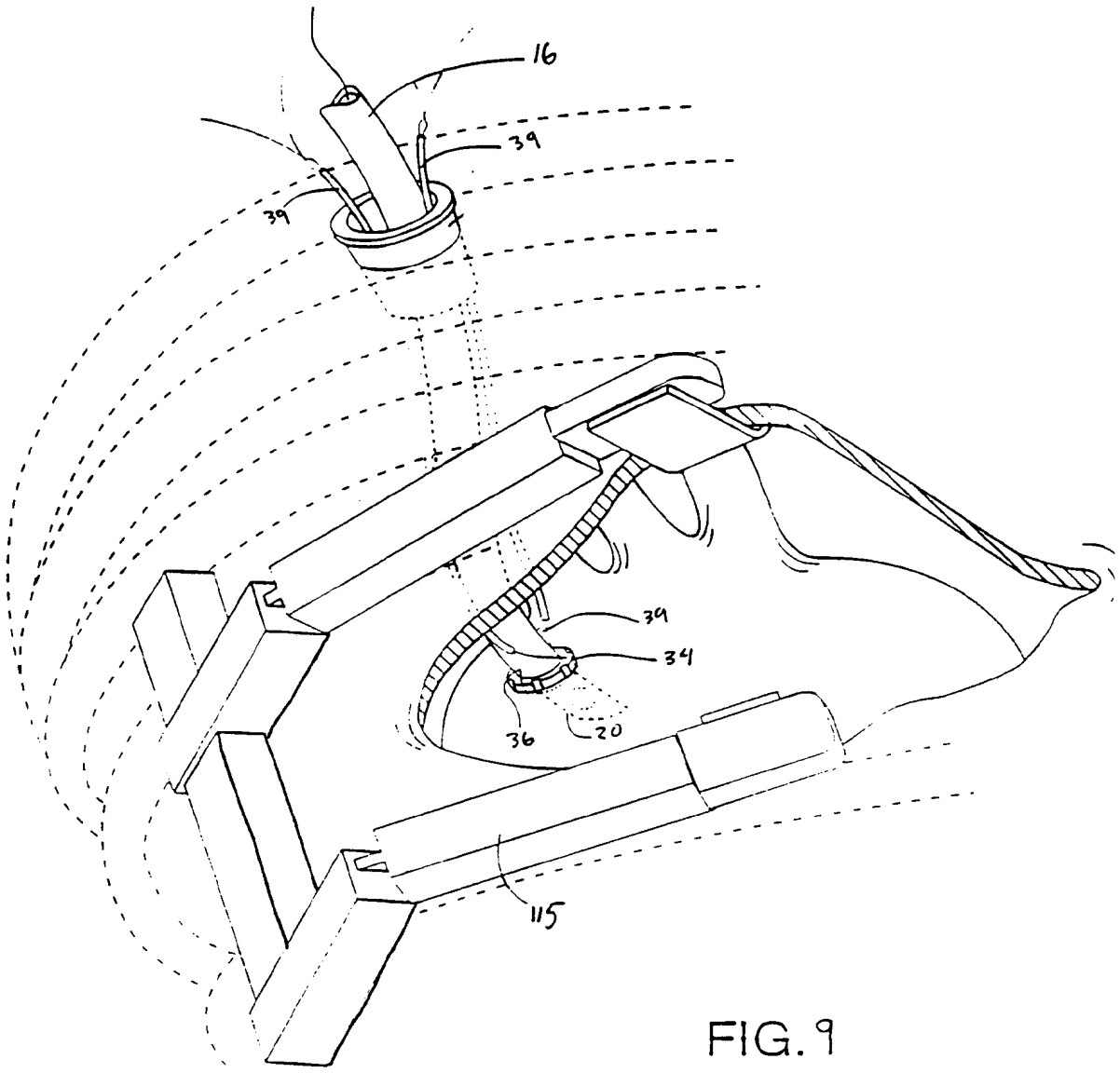


FIG. 9

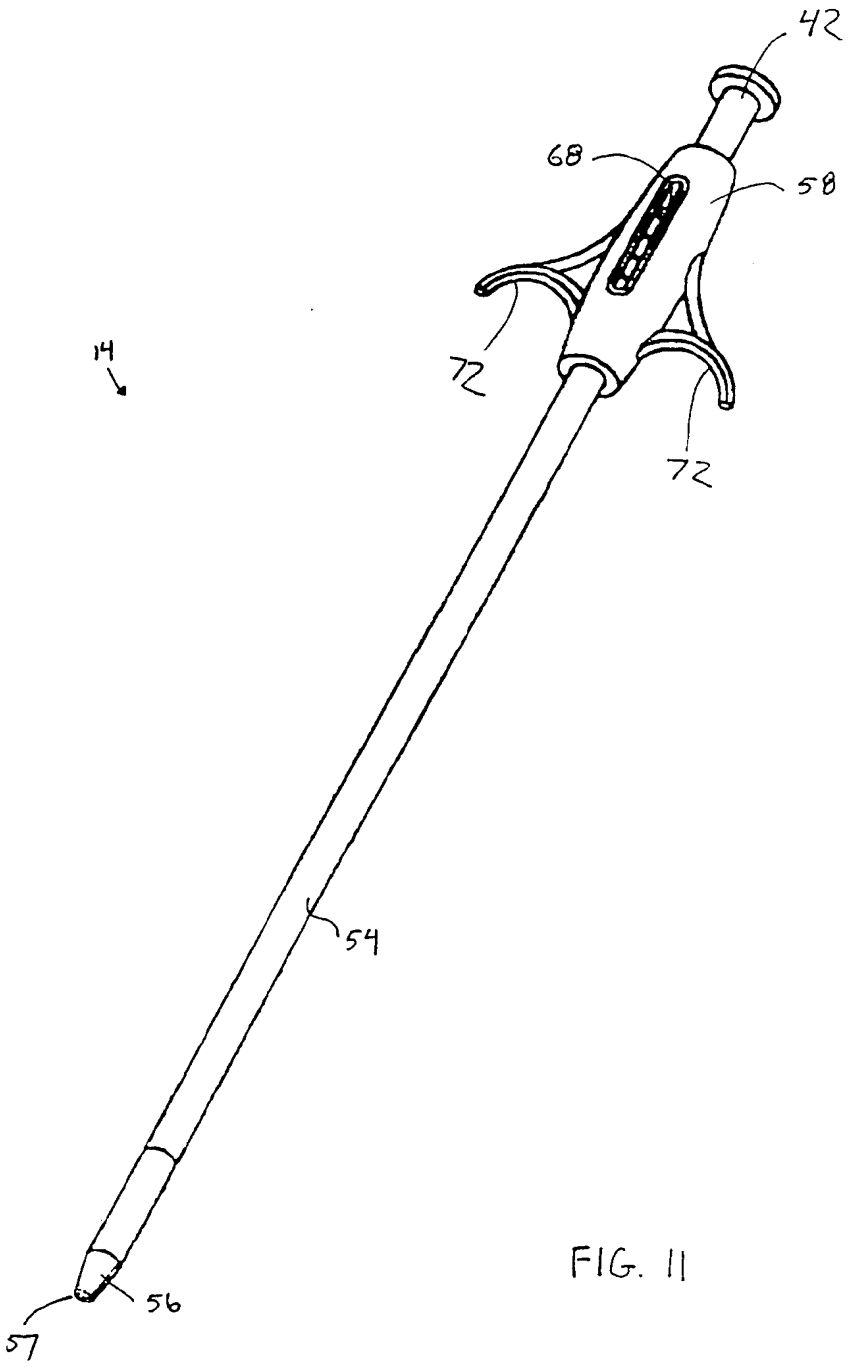


FIG. 11

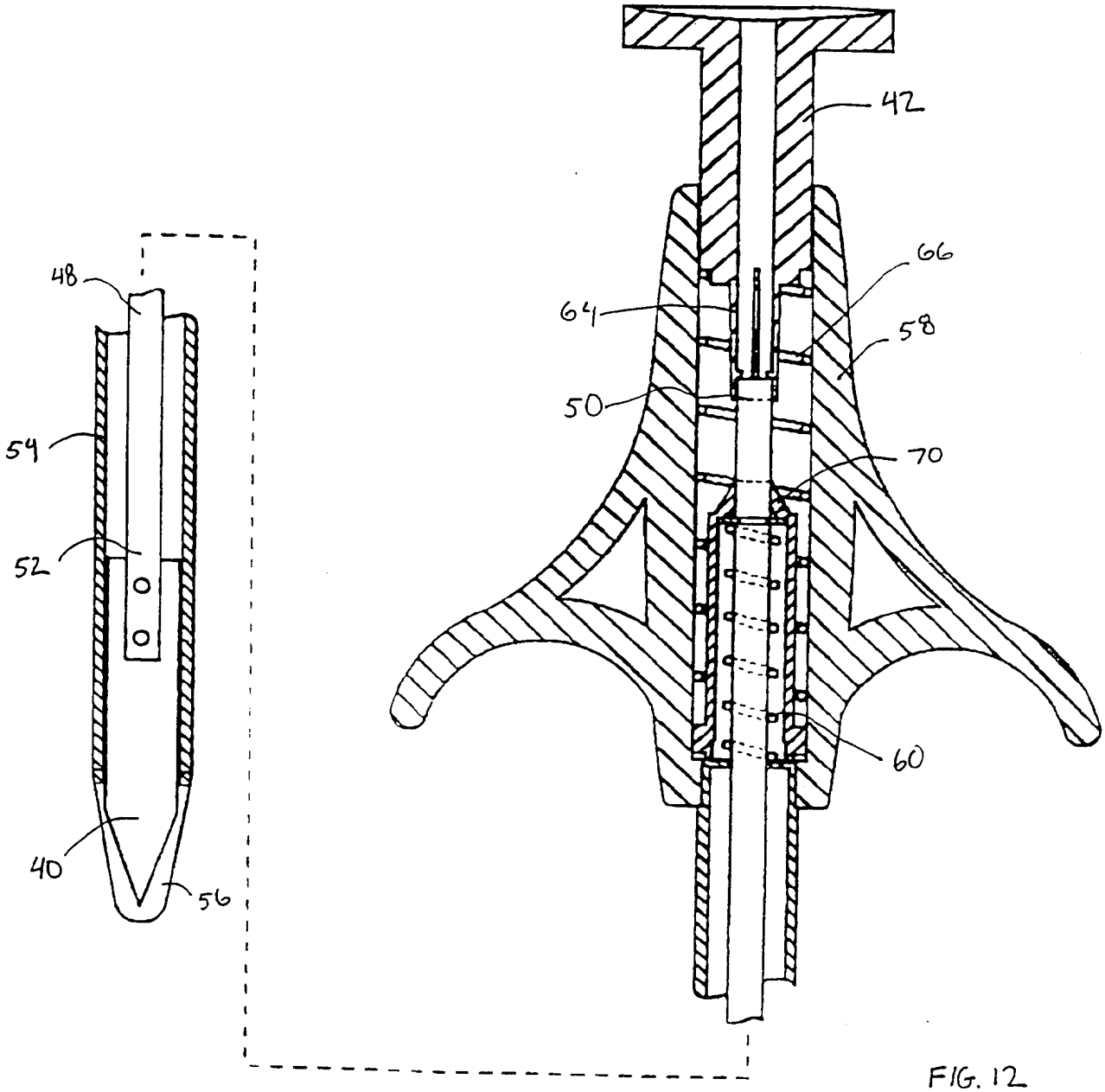


FIG. 12

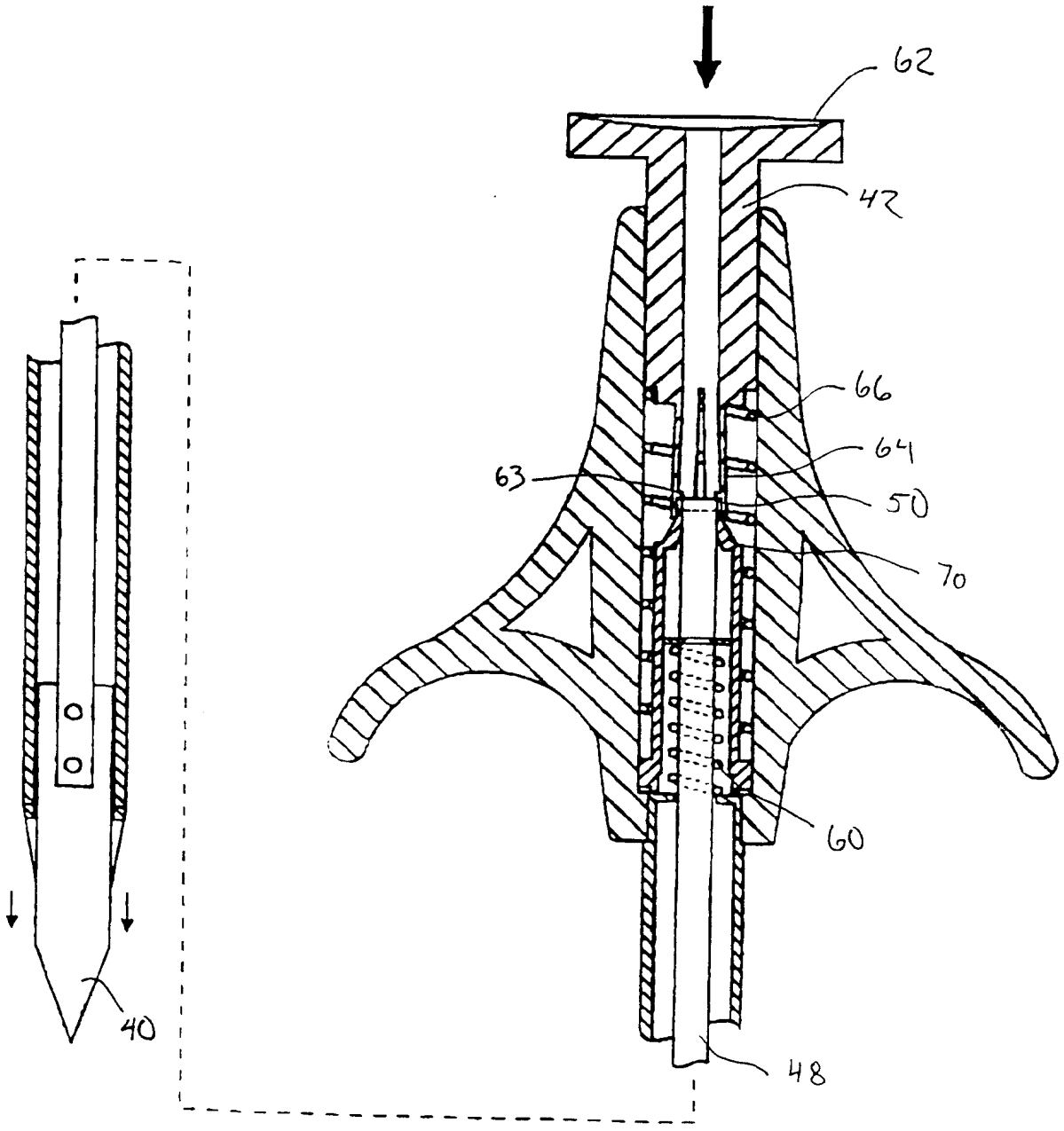


FIG. 13

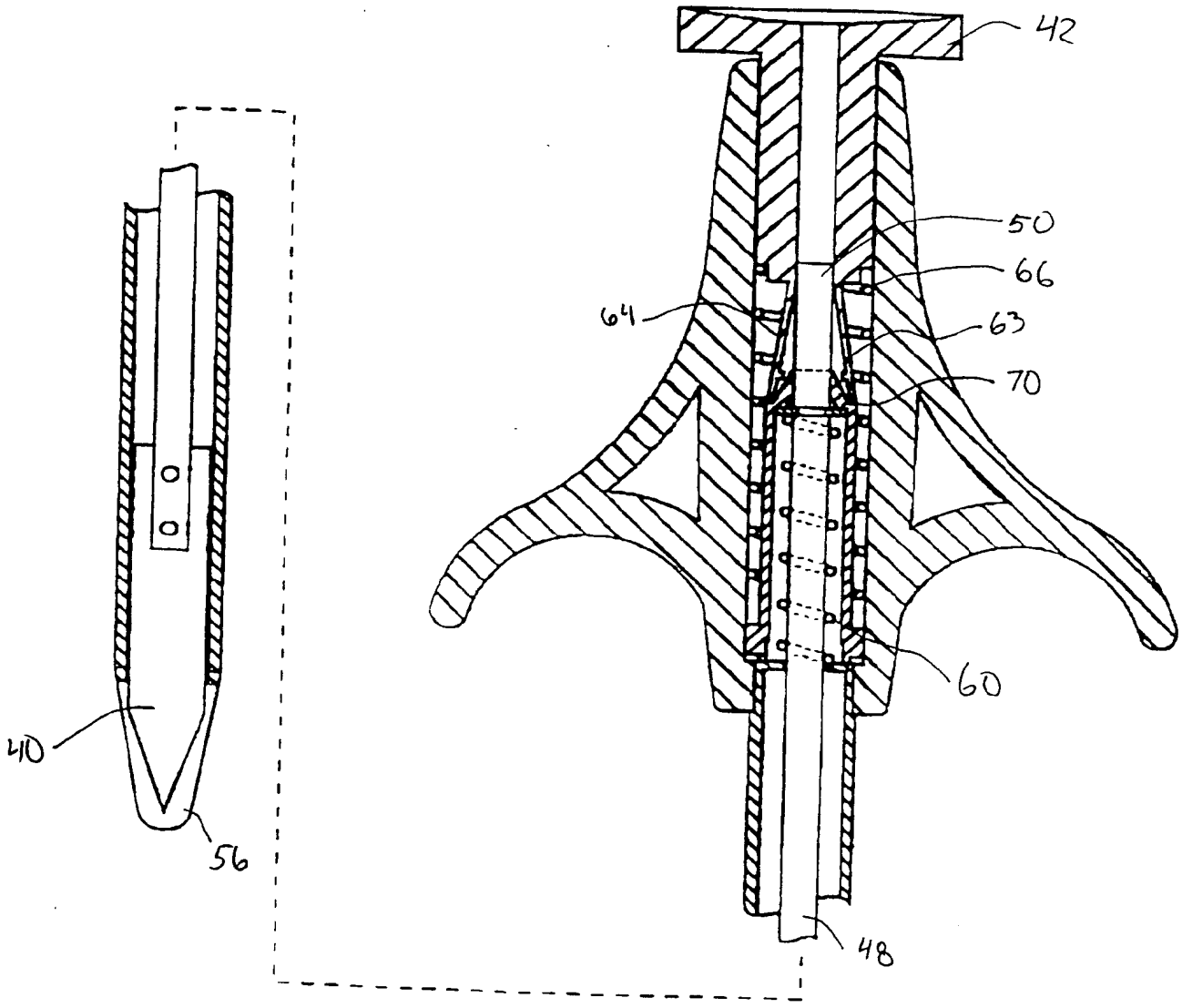


FIG. 14

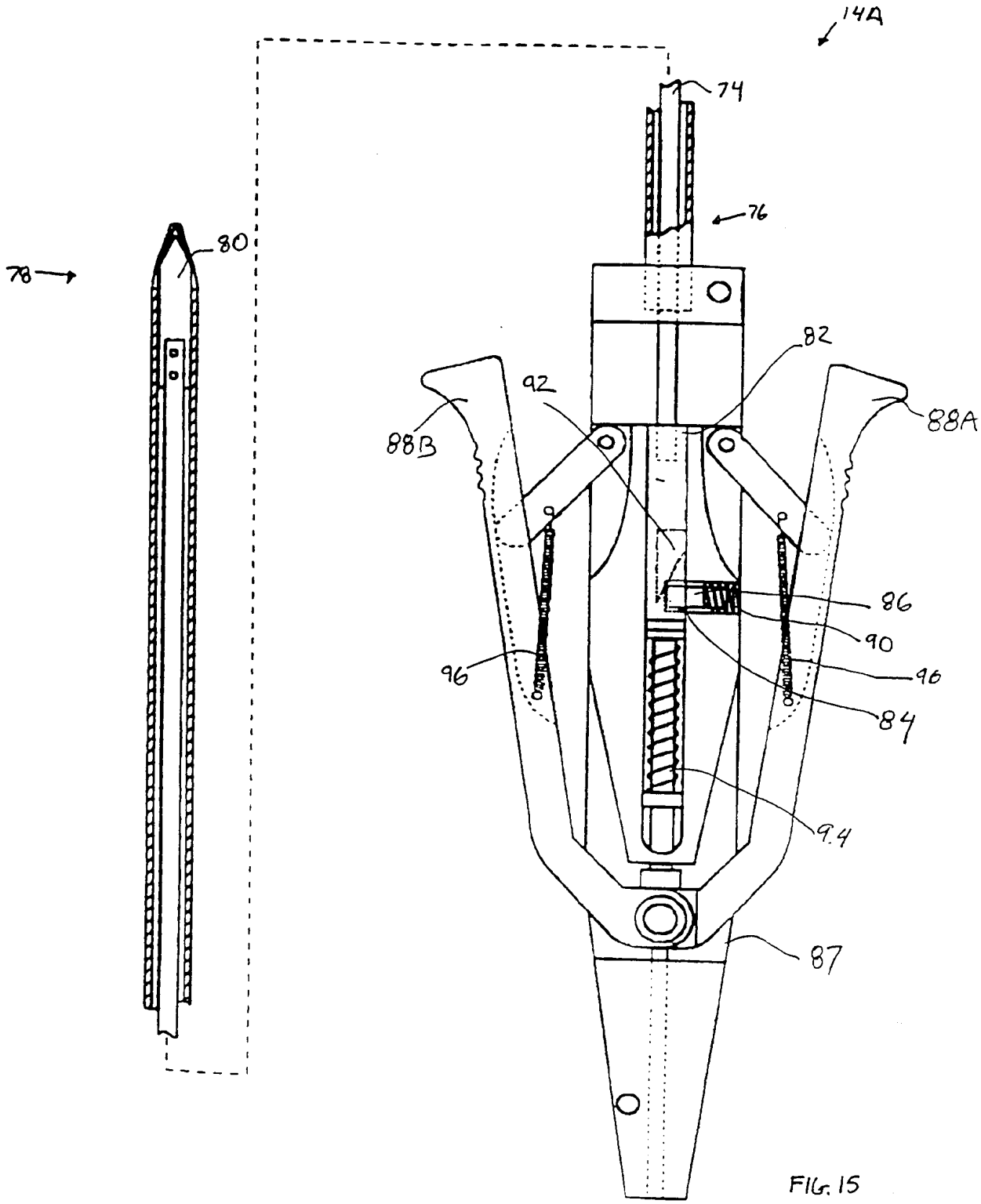


FIG. 15

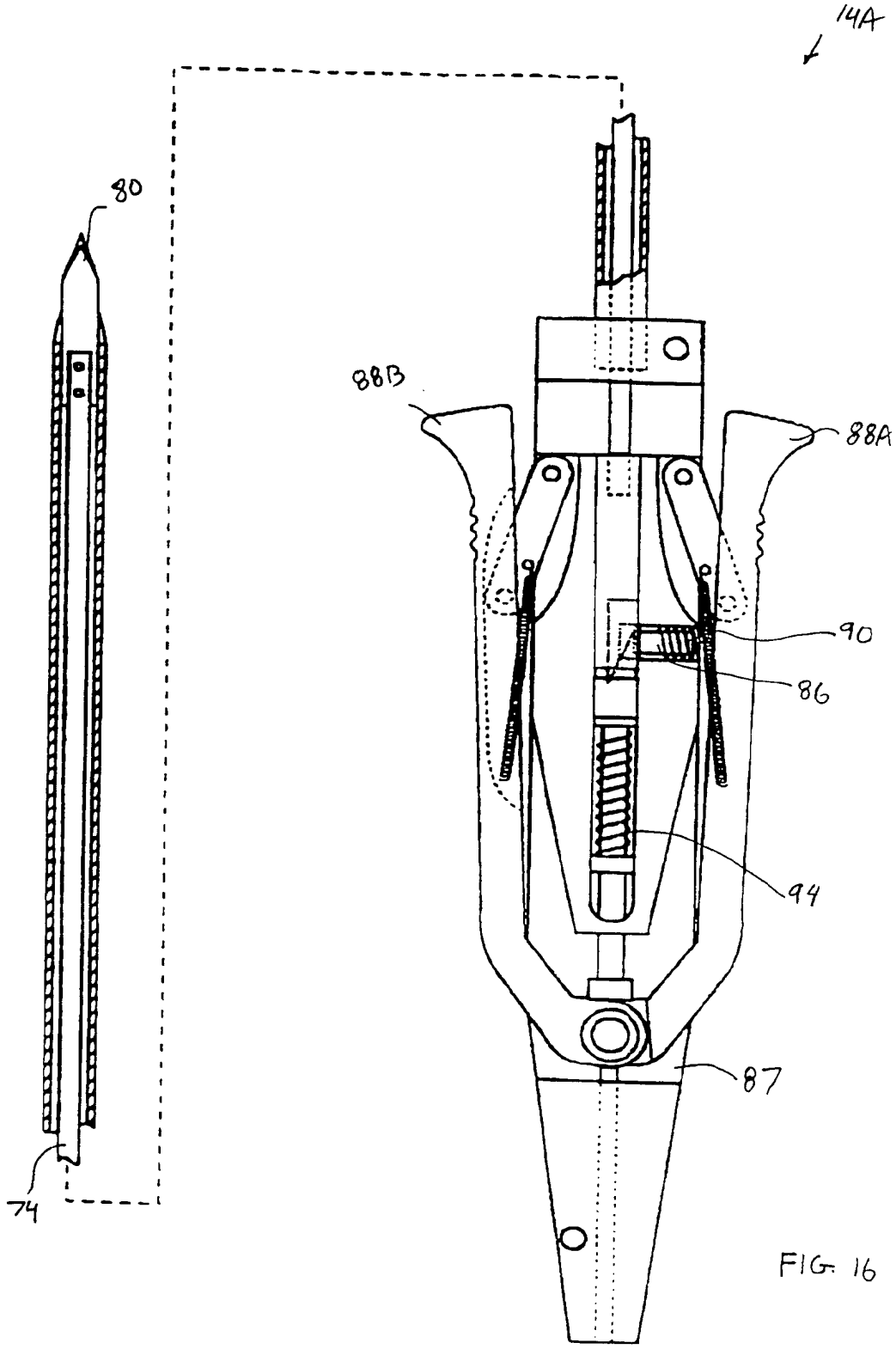


FIG. 16

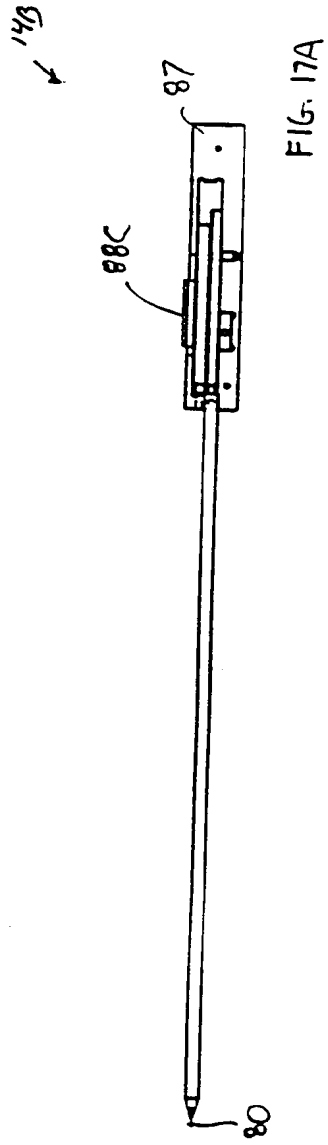


FIG. 17A

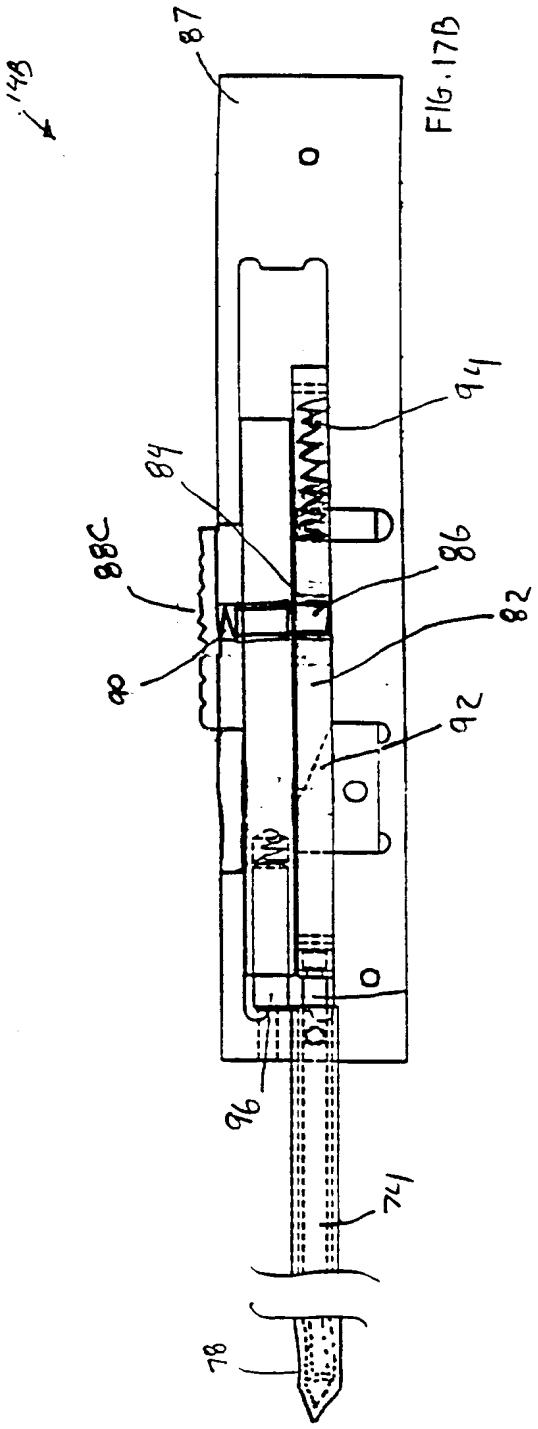


FIG. 17B

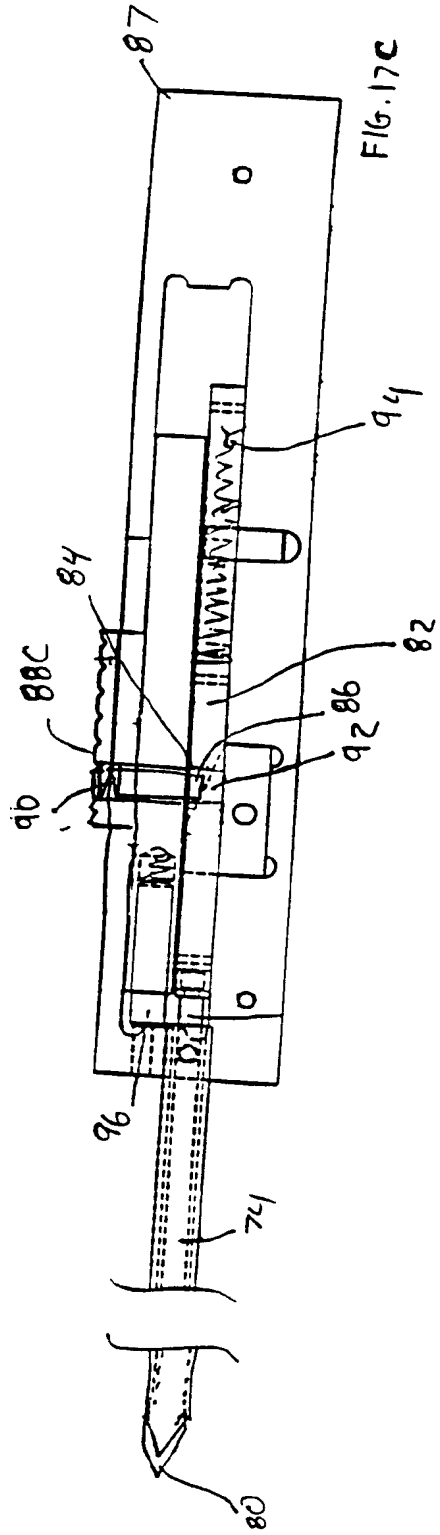


FIG. 17C

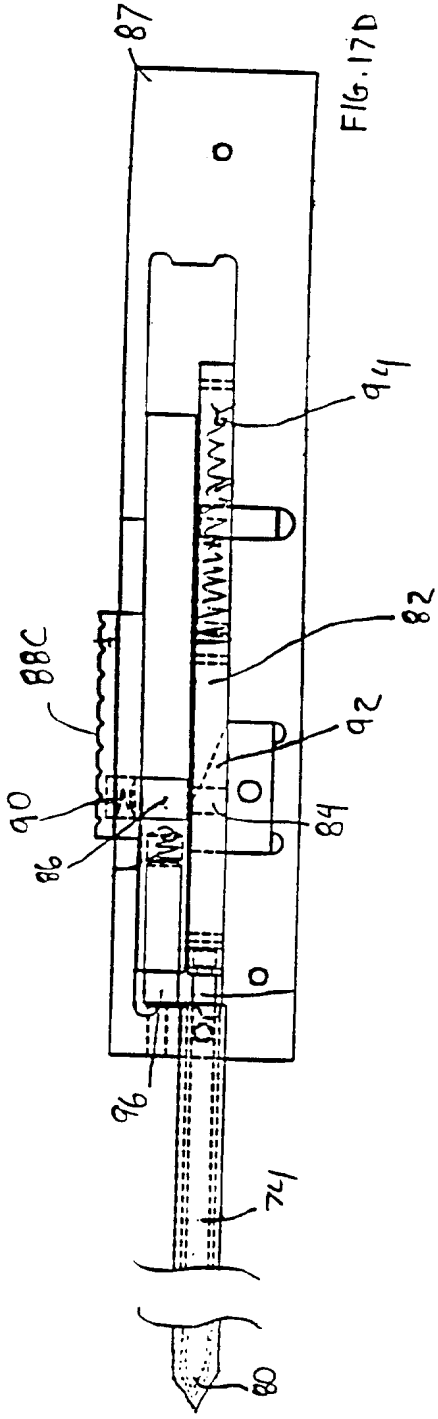


FIG. 17D

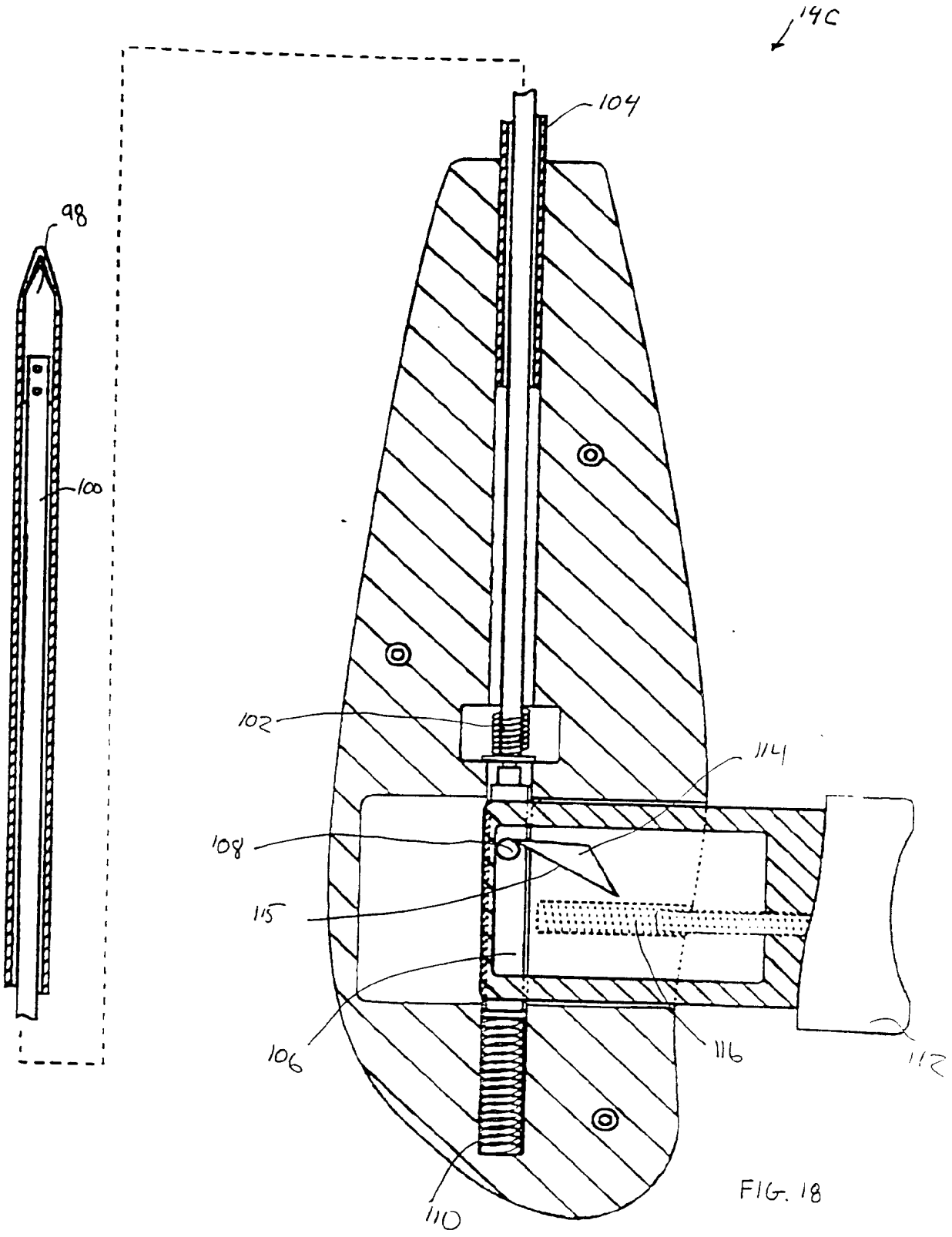


FIG. 18

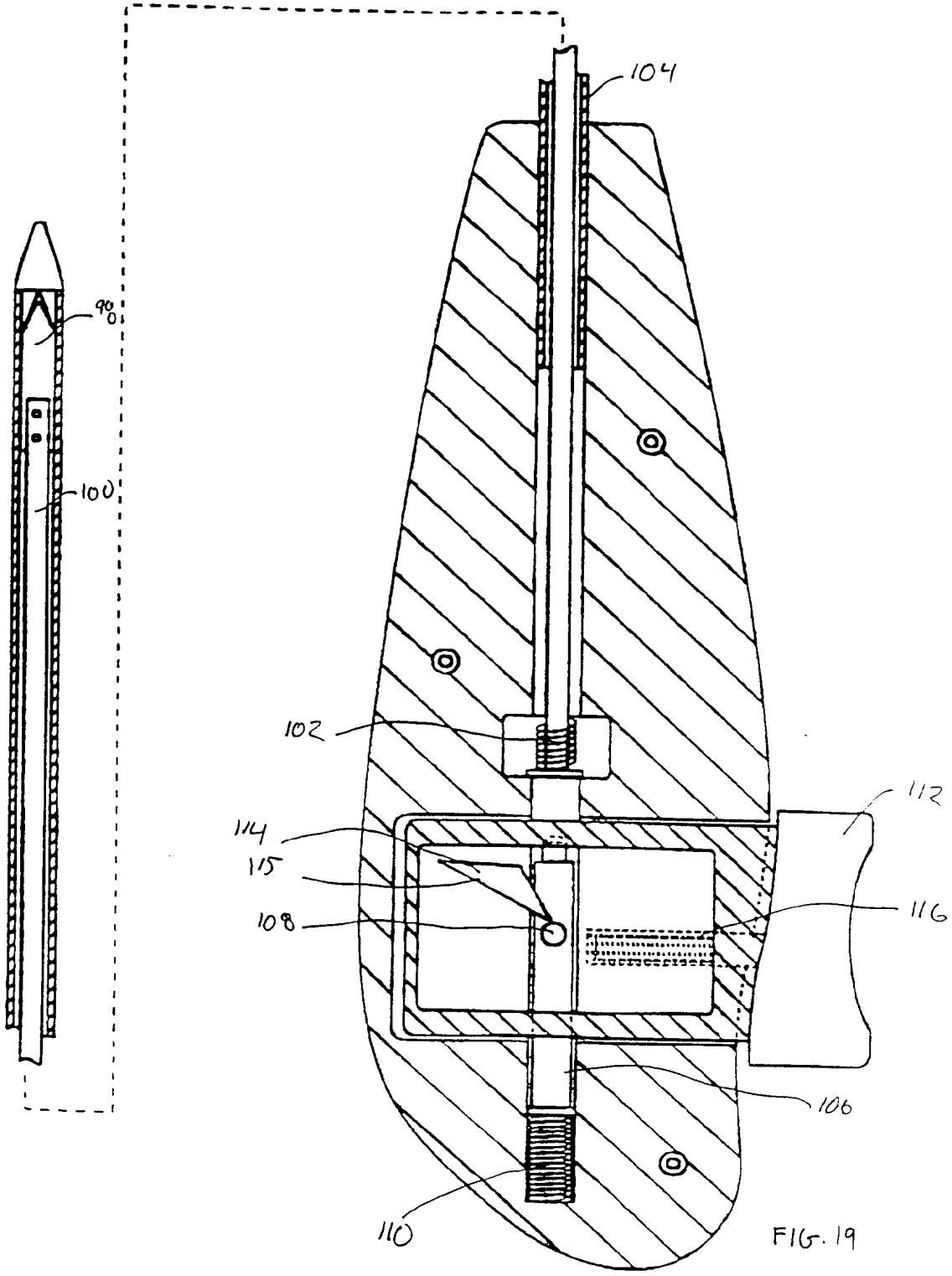


FIG. 19

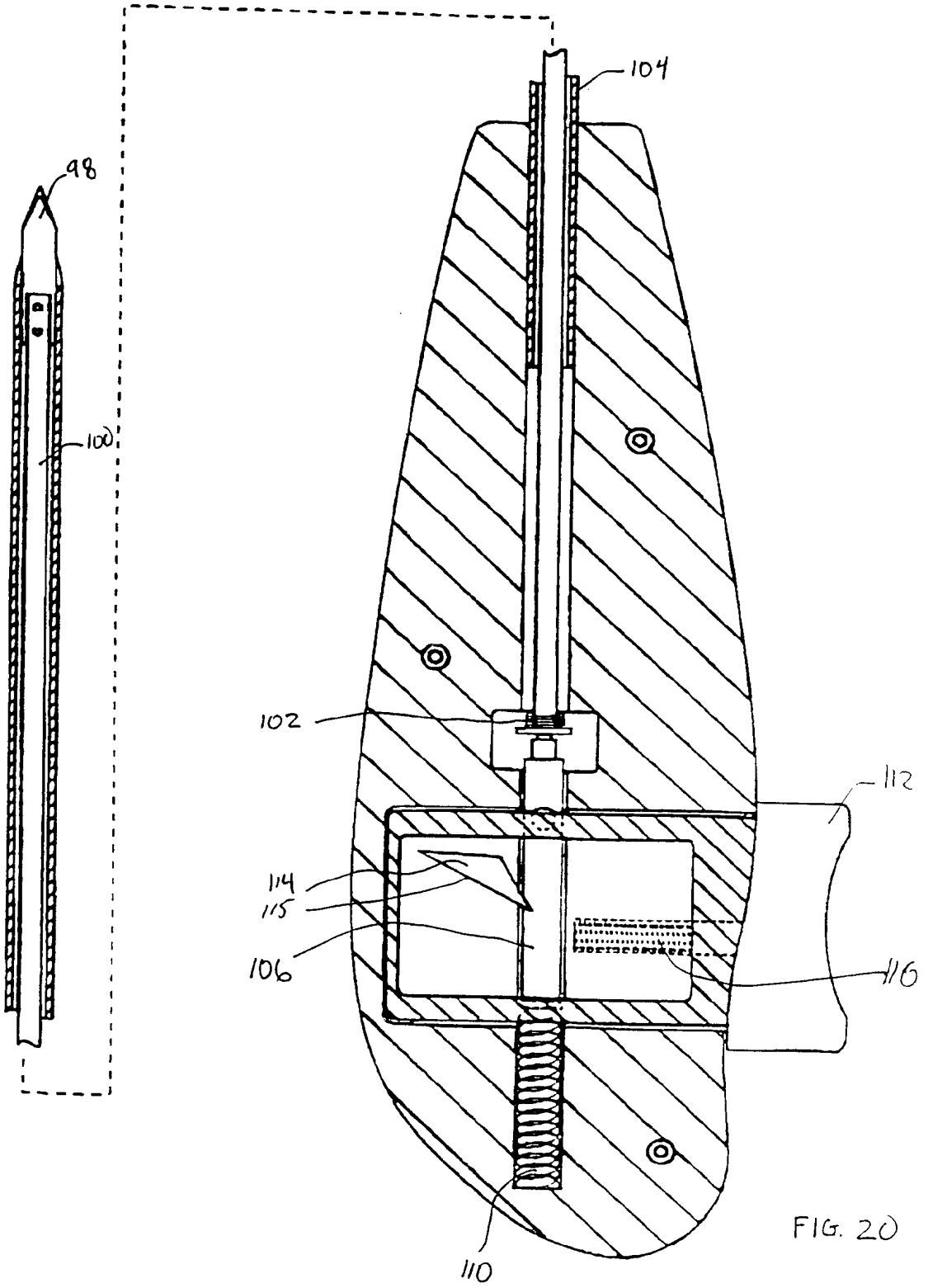


FIG. 20

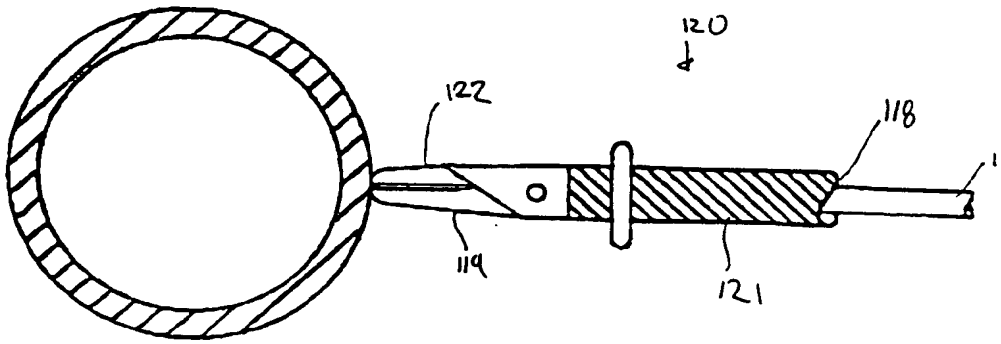


FIG. 21A

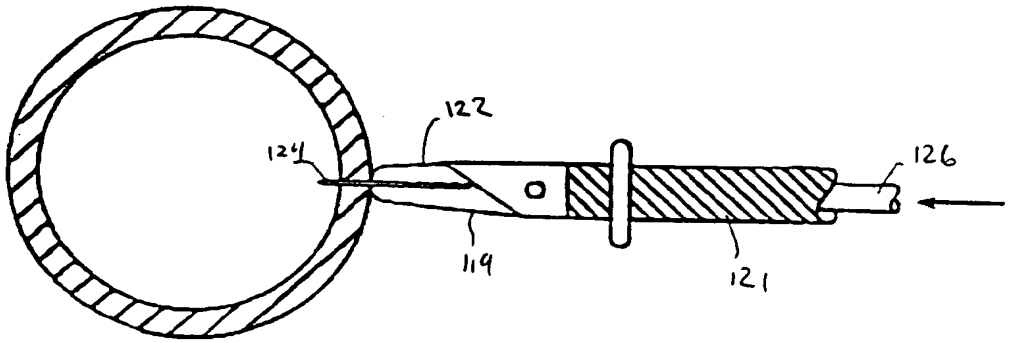


FIG. 21B

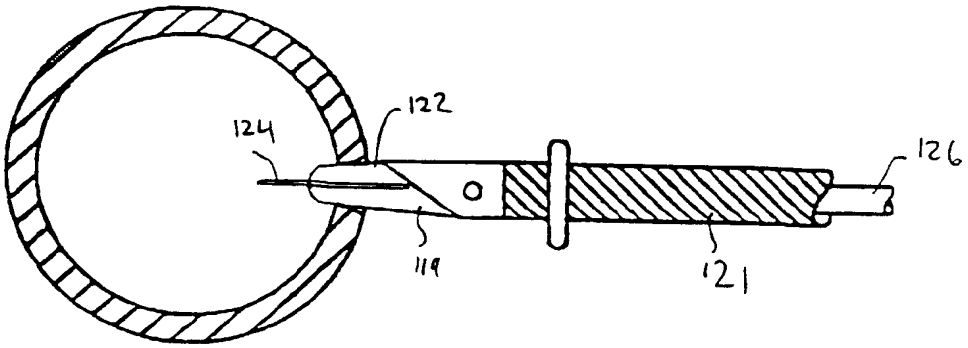


FIG. 21C

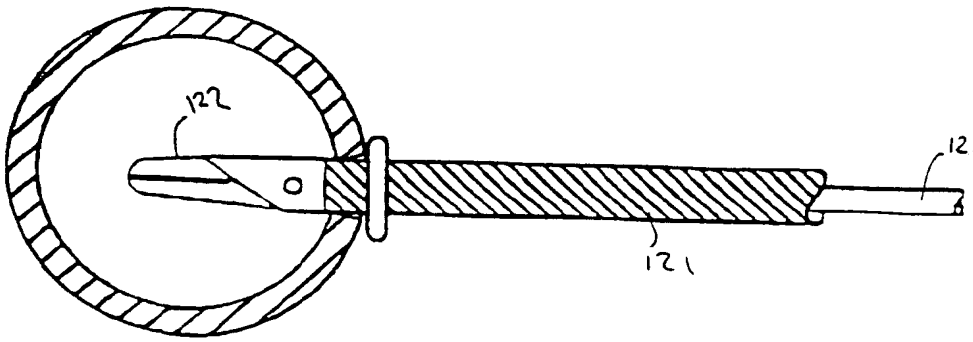


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/02739

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/00
US CL :606/170

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/1, 159, 170, 184, 185

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 518,600 A (HALLMAN) 24 April 1894, see entire document.	1-22, 39-42, 81-85
A,P	US 6,030,402 A (THOMPSON et al.) 29 February 2000, see entire document.	1-85

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 03 JUNE 2001	Date of mailing of the international search report 27 JUN 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer WILLIAM W. LEWIS Telephone No. (703) 308-0060

Form PCT/ISA/210 (second sheet) (July 1998)★